

HOLOGIC®



Perilynx™ System

User Manual

IMPORTANT: Read the entire manual before operating the PeriLynx™ System



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Revision History

Revision	Date	Description
AW-24885-001	5-2022	Add language selection instructions. Add notice regarding reporting serious incidents. Add security information.
AW-24885-001 Rev. 002	1-2023	Administrative changes.

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Section 1 – Introduction



For *In Vitro* Diagnostic Use Only
To be used by trained medical personnel only

Intended Use

The Hologic PeriLynx™ system is an *in vitro* diagnostic device intended to be used in conjunction with the Rapid fFN® 10Q cassette, the Rapid fFN® control kit, and the PeriLynx™ QCette® for the detection of fetal fibronectin (fFN) in cervicovaginal secretions. For near-patient use. Refer to the directional insert for the Rapid fFN 10Q cassette for detailed intended use information.

General Description

The PeriLynx™ analyzer is an electronic optical reflectance device that converts a colorimetric reaction from a cassette into a digitized format. The PeriLynx analyzer is not an automated device. The data are analyzed using multiple parameters, including a comparison of sample data to calibration data. The analyzer reports the fFN concentration in the clinical specimen.

The analyzer reports fFN concentrations ranging from 0–500 ng/mL. Concentrations greater than 500 ng/mL are reported as >500 ng/mL. The result is reported as invalid if specific internal test criteria have not been met.

Components of the Analyzer

The major components of the analyzer are the touch screen and the cassette insertion site.



Touch screen

Use the touch screen to enter data, select options, and move through the menus.

See Section 3 — General Operating/Testing Instructions, for a full description of using the touch screen.

Cassette insertion site

The Cassette Insertion Site contains a slightly concave trough designed to capture any fluids that may have been spilled while applying sample to the cassette. This area of the instrument should be cleaned regularly (see Section 5 — Care of the Analyzer).

Note: For the detection of fetal fibronectin (fFN) in cervicovaginal secretions, insert a **Rapid fFN 10Q Cassette** or **PeriLynx QCcette** only.

Displayed/Printed Results

Each menu function result is displayed on the analyzer touch screen. With Auto Print ON, the result is automatically printed. Each printed result requires one printer label. Results can be printed from any data record screen either immediately after a test or in Access Data mode. The example below demonstrates the display and printout of a patient test.

Example: Displayed/Printed Results of Patient Test

The screenshot shows a dark blue interface with white text. At the top, it says 'Test Patient' on the left and '3/1/2016 16:42' on the right. Below this, a light blue bar contains 'Sample ID: 16976565' and 'Cassette Lot: F1067'. The main result is 'fFN CONC: 160 ng/mL' in large white font. To the left, it shows 'Date: 3/1/2016' and 'Time: 16:42'. To the right, there is a box titled 'Internal Controls' containing 'Analyzer QC: ✓ PASS' and 'Cassette QC: ✓ PASS'. At the bottom, there are two buttons: 'Print' (light blue) and 'Finish' (light green).

Displayed

The printed label is white with black text. It starts with 'HOLOGIC®' at the top, followed by 'Rapid fFN 10Q Test Result'. The main result is 'fFN CONC: 160 ng/mL'. Below that, it shows 'TIME: 16:42' and 'DATE: 3/1/2016'. Further down, it lists 'SAMPLE: 16976565', 'USER: 1001', 'CASSETTE LOT: F1067', 'CALCODE: D6F7M-FEH33', and 'ANALYZER ID: 0000000014'. At the bottom, it says 'INTERNAL CONTROLS', 'ANALYZER QC: PASS', and 'CASSETTE QC: PASS'.

Printed

Specifications

Power Supply	UL +24 VDC listed power supply
Memory Capacity	50 Calibration Records 50 QCette Records 50 Control Records 1000 Patient Records
Touch screen	5-inch diagonal display with 480 x 800 resolution and 256 colors. Resistive interface.
Dimensions	Length — 10 inches (25.4 cm) Width — 7.5 inches (19.05 cm) Height — 4 inches (10.16 cm) Weight — 2.4 pounds (1090 g)
Storage Temperature	15° to 30°C 59° to 86°F
Operating Temperature	15° to 30°C 59° to 86°F
Operating Humidity	20% to 80%, non-condensing

Sound level, analyzer	Maximum A-weighted sound pressure level at the typical user's position and at a radius of 1 meter around the analyzer is 56 dB.
A.C. Supply	100-240VAC 50-60 Hz 2.1A
Input Connector	Coaxial power plug with positive center conductor
Output Connectors	9-pin RS-232 connector 3 host USB connectors Ethernet connector Printer power connector

Cautions and Warnings

There are no known hazards associated with the PeriLynx system when it is operated in accordance with the instructions in this manual. However, you should be aware of situations that can result in serious injury. If any serious incident occurs related to this device or any components used with this device, report it to Hologic Technical Support and the competent authority local to the patient and/or user.



WARNING! Ensure that the analyzer power adapter is connected to an AC electrical outlet that provides voltage and current specified by Hologic. Use of an incompatible power receptacle can cause shock and fire hazard.

CAUTION! Use only the power adapter supplied by Hologic. Use of an incompatible power adapter can damage the internal components.

CAUTION! Always turn off the power and unplug the power adapter before cleaning the exterior of the analyzer. Fluid can damage internal components. DO NOT clean the power adapter.

CAUTION! Extreme heat can damage the display and other electronic components.



WARNING! Never apply cleaning reagents by spray as the liquid may leak into the analyzer causing damage to the electrical components or possibly electrical shock to the user.

CAUTION! Do not immerse the analyzer in liquid. Fluid can damage internal components.

CAUTION! Do not clean the touch screen display with undiluted bleach solution or other solvents. Caustic cleaning solutions can damage the touch screen.

CAUTION! Use appropriate laboratory procedures for handling biohazardous materials.

If this equipment is used in a manner not specified by the manufacturer, then the protection provided by the equipment may be impaired.

FCC Notice:

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

FCC Warning:

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

Note: *The use of a non-shielded interface cable with this equipment is prohibited.*

CE Notice:

This equipment has been tested and found to be in compliance with the following standards per the IVD Directive:

EN61326-2-6	Electrical Equipment for Measurement, Control and Laboratory Use; EMC Requirements; <i>In Vitro Diagnostic</i> (IVD) Medical Equipment.
EN61010-2-101	Electrical Equipment for Measurement, Control and Laboratory Use; Part 101; Particular requirements for <i>In Vitro Diagnostic</i> (IVD) Medical Equipment. This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference. The electromagnetic environment should be evaluated prior to operation of the device. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

This equipment also complies with the following safety standards:

- UL61010-1 Safety Requirements for Electrical Equipment for Laboratory Use Part 1: General Requirements, with an ETL or equivalent Approval Mark
- ICES-003 Industry Canada Regulation: Interference-Causing Equipment Standards - Digital Apparatus
- CAN/CSA C22.2 No. 61010-2-101
Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements, with ETL or equivalent Approval Mark

Disposal of Electrical & Electronic Equipment

Waste Electrical and Electronic Equipment (WEEE)

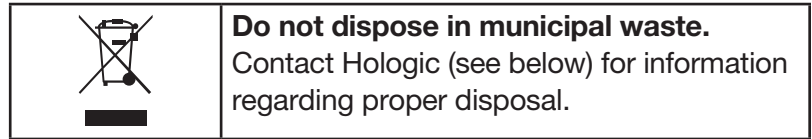
Hologic is dedicated to meeting country specific requirements associated with the environmentally sound treatment of our products. Our objective is to reduce the waste arising from our electrical and electronic equipment. Hologic realizes the benefits of subjecting such WEEE equipment to potential reuse, treatment, recycling or recovery to minimize the amount of hazardous substances entering the environment.

Your responsibility

As a Hologic customer, you are responsible for ensuring that devices marked with the symbol shown below are not placed into the municipal waste system unless authorized to do so by the authorities in your area. Please contact Hologic (see below) prior to disposing any electrical equipment provided by Hologic.

Symbol used on the instrument

The following symbol is used on this instrument:



Reclamation






Hologic will provide for the collection and proper reclamation of electrical devices we provide to our customers. Hologic strives to reuse Hologic devices, subassemblies, and components whenever possible. When reuse is not appropriate, Hologic will ensure the waste material is properly disposed of.



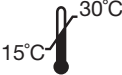


Hologic Contact Information


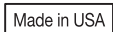

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<p>Authorized Representative in the European Community</p>	<p>Hologic BV Da Vincilaan 5 1930 Zaventem Belgium</p>




Symbols Used on the Instrument

The following symbols may appear on this instrument or its packaging:

	Caution, consult instructions for use
	Waste Electrical and Electronic Equipment - contact Hologic for disposal of the instrument.
	Catalogue Number
	Serial Number
 www.hologic.com/ifu	Consult instructions for use

	Manufacturer
	Authorized Representative in the European Community
	Store between 15°C and 30°C
	Biological risks
	Product meets the requirements for CE marking in accordance with EU-IVD Regulation 2017/746

	<p>Information is applicable only in the USA and Canada</p>
	<p>Made in USA</p>
	<p>For <i>in vitro</i> diagnostic testing</p>

	<p>The ETL Mark is proof of product compliance to North American safety standards. Authorities Having Jurisdiction (AHJs) and code officials across the US and Canada accept the ETL Listed Mark as proof of product compliance to published industry standards</p>
	<p>For near-patient testing</p>
	<p>Direct current (DC)</p>

Section 2 – Installation

General

This section provides detailed installation instructions for the PeriLynx system. Follow installation steps carefully to insure proper installation and operation.

Environmental Factors

The PeriLynx system has been designed to be safe under the following conditions:

- Indoor use;
- Altitudes up to 2000 m;
- Maximum relative humidity of 80% for temperatures up to 30°C;
- Pollution Degree II, in accordance with IEC 61010-1 Category II. The PeriLynx system is for use only in an office or a clean laboratory environment.
- The operating temperature should be held relatively constant. The optimum operating temperature is 15° to 30°C (59° to 86°F). Before operating, allow the instrument to equilibrate to room temperature.

Place the instrument away from direct sunlight and away from locations subject to extreme temperature variations (e.g., near open windows, ovens, hot plates, radiators, etc.).

Security

Limit Access to Trusted Users

The PeriLynx analyzer is a non-networked, stand-alone device. There are minimum cybersecurity risks to the system, but someone with physical access to the system could cause unintentional or intentional harm. Hologic recommends that the analyzer should be located in an area that is only accessible to users as the customer sees fit.

In the event of a non-functioning analyzer, contact Hologic Technical Support.

Cybersecurity Safeguards

Hologic incorporates secure design principles into the product development lifecycle to minimize cybersecurity risks. The following safeguards are provided in the PeriLynx analyzer:

- Access to update software is limited to Hologic personnel.
- The device is stand-alone and does not connect to an external network.
- The analyzer is designed so that a customer can require a password to view and print patient information.

Cybersecurity Updates

Hologic continually evaluates software updates, security patches, and the effectiveness of the implemented security safeguards to determine if updates are needed to mitigate emerging threats. Hologic will provide validated software updates and patches as needed throughout the lifecycle of the medical device to continue to assure its safety and effectiveness.

Unpacking

PeriLynx analyzer

Carefully remove the analyzer and accessories from the shipping carton.

Inspect the carton and the analyzer for visible signs of damage. If the analyzer is damaged, immediately contact the carrier and Hologic Customer Service.

The carton should contain the following parts/accessories:

- PeriLynx analyzer
- AC adapter and power cord (one or more for international compatibility)
- User manual
- PeriLynx QCette®

Note: Retain the shipping carton for future use. If the analyzer needs to be shipped, use the original shipping carton.



Printer

Carefully remove the printer and accessories from the shipping carton. Inspect the carton and the printer for visible signs of damage. If the printer is damaged, immediately contact the carrier and Hologic Customer Service.

The printer carton should contain the following parts/accessories:

- Printer
- Printer labels (1 roll)
- Power cord
- USB cable

Note: Retain the shipping carton for future use. If the printer needs to be shipped, use the original shipping carton.



Barcode scanner (optional)

A barcode scanner is available from Hologic for entering data into the analyzer. This barcode scanner is the only barcode scanner for use with the PeriLynx system. If your order included the optional barcode scanner, carefully remove the barcode scanner and accessories from the shipping carton. Inspect the carton and the barcode scanner for visible signs of damage. If the barcode scanner is damaged, immediately contact the carrier and Hologic Customer Service.

Follow all of the instructions provided by the barcode scanner manufacturer regarding the safe use of the barcode scanner.

The barcode scanner carton should contain the following parts/accessories:

- Barcode scanner
- Stand



System Setup

1. The analyzer and printer should be placed on a flat, level surface. Verify that the power switch on the back of the analyzer is set to the off (0) position.

Note: Do not install any of the Dymo Label software that comes with the printer.

2. Plug the power cable jack into the receptacle labeled 24V DC on the bottom of the printer. Plug the other end of the cable into the PeriLynx analyzer.
3. Insert the USB cable into the receptacle labeled USB on the bottom of the printer. Route the USB cable and the power cable through the cable channel and set the printer upright on a flat surface. Plug the other end of the USB cable into any of the USB ports on the analyzer.



System

(Photo includes optional barcode scanner)



Printer



Analyzer

4. Use the AC cord corresponding to the room power outlets. Plug the output jack from the power adapter into the rear of the analyzer. Plug the wall mount adapter into an AC power outlet.

Caution: Only the power adapter provided with the PeriLynx analyzer may be used. Any substitutions can result in damage to the PeriLynx analyzer and printer.

5. To connect the optional barcode scanner, plug the USB cable of the scanner into any of the USB ports on the analyzer.

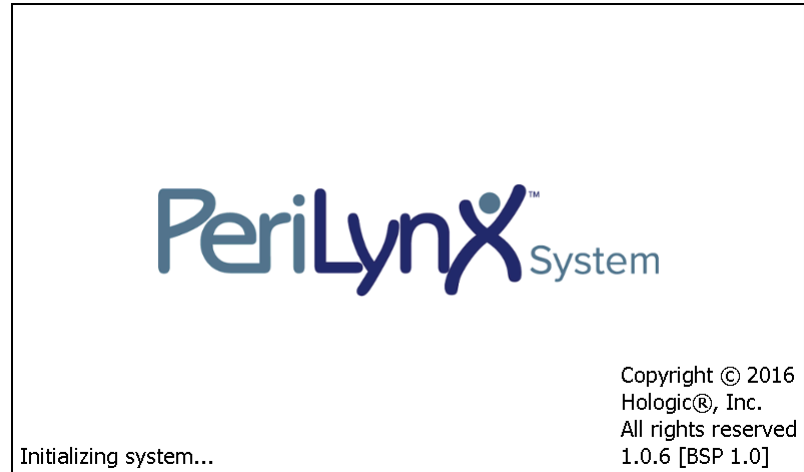
Getting Started

Turn the analyzer power switch to the on (I) position. The power switch is located on the back of the instrument. (If the analyzer does not turn on, see Section 7 – Troubleshooting, Item 1.)

Upon power up, the analyzer displays the Hologic logo and then PeriLynx system logo with the message “Initializing system...” for 60 seconds. Then, the analyzer performs a self-test of the analyzer components.

If there is a problem after the self-test, a beep will sound to indicate an error and an error message will be displayed. If an error message is displayed, refer to the troubleshooting section of the manual.

If the printer is not connected, an error message will be displayed.



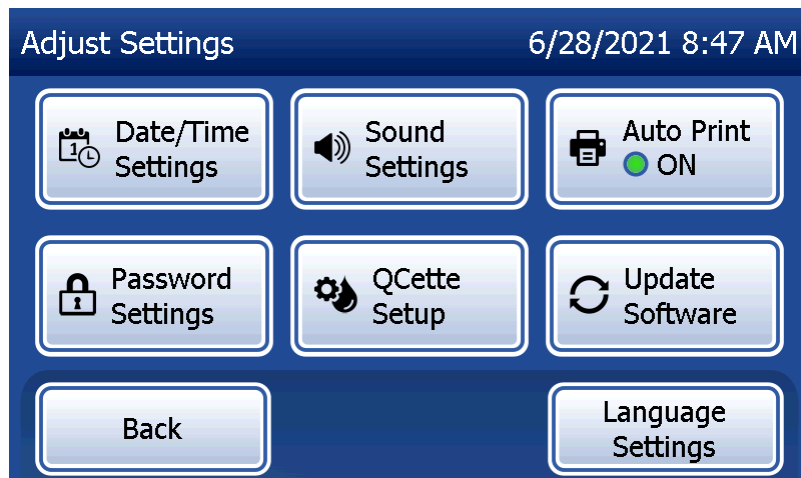
Once the self-test is complete, the display will change to the Main Menu. The date and time may need to be reset for your time zone.



Setting the Date and Time

1. From the Main Menu, select **Adjust Settings**.
2. Touch **Date/Time Settings** and follow the prompts.

For more details about setting the date and time, see Section 4 — Software Functions — Detailed Descriptions.



Factory Default Settings

The PeriLynx system uses the following default settings. To customize the unit to your laboratory requirements, refer to Section 4 — Software Functions — Detailed Descriptions.

The default settings are as follows:

Auto Print

Factory setting is Auto Print ON. After every result, the printer will generate a printed result.

Date format

The default setting is MM/DD/YY.

Time format

The default setting is 24 hour time.

Sound settings

The default setting is for the audible tone (beep) to be turned on at a volume of 5.

Password settings

The default setting has the password disabled.

Shutdown

The system may be left plugged in and idle when not in use. If the system is to be shut down make sure it is idle. Move the power switch on the back of the analyzer to the off position.

Extended Shutdown

If the system is to be turned off for a long period of time, or taken out of use, power off the analyzer as described above. Completely remove power from the device by unplugging the power cord from the electrical outlet.

Section 3 – General Operating/Testing Instructions

After instrument installation, the PeriLynx analyzer can be operated on a day-to-day basis by using the following procedures. Read Section 4 for detailed descriptions of displays, prompts and operating sequences.

Starting the System

1. Turn the analyzer power switch to the on position. The power switch is located on the back of the instrument. (If the analyzer does not turn on, see Section 7, Troubleshooting, Item 1.)

Upon power up, the analyzer displays the message “Initializing system...” for 60 seconds. Then, the analyzer will perform a self-test of the analyzer components.

If there is a problem after the self-test, a beep will sound to indicate an error and an error code will be displayed. If an error code is displayed, refer to the troubleshooting section of the manual. Verify the date and time are correct. See Section 4 – Software Functions – Detailed Descriptions, for setting Date/Time.

2. Once it is connected to the analyzer, the printer is continuously powered on. Ensure labels are in the printer. See Section 6 – Printer, for loading printer labels.

Overview of PeriLynx Analyzer Main Menu

Main Menu	Purpose
Test Patient	Runs the Rapid fFN 10Q test on a patient sample.
Run QCette QC	Compares functional parameters of the QCette against those of its original setup. Ensures the analyzer is functioning properly. Performed daily.
Run Liquid QC	Runs the liquid control samples on the analyzer to ensure the PeriLynx System functions properly. Performed at installation and with every cassette lot change or shipment.
View Reports	View/print the results of patient tests, QCette and control checks and system calibration results. Allows for transfer of data via the data port.
Enter New Calibration Code	Allows the calibration code for a lot of cassettes to be entered and stored into analyzer memory. Performed at installation and with every cassette lot change.
Adjust Settings	Allows change to date/time, sound, Auto Print, and password settings. Allows QCette setup.
Update Software	Allows the software version to be updated.

The main menu also displays the status of the QCette QC.

Typical Menu Item Sequences

Upon System Installation	Routine Daily Use	New Lot of Cassettes
Date /Time Settings	Run QCette QC	Enter New Calibration Code
Select Auto Print On/Off	Test Patient	Run QCette QC
QCette Setup	View Reports	Run Liquid QC
Enter New Calibration Code		Test Patient
Run QCette QC		View Reports
Run Liquid QC		
Test Patient		
View Reports		

Using the Touch Screen

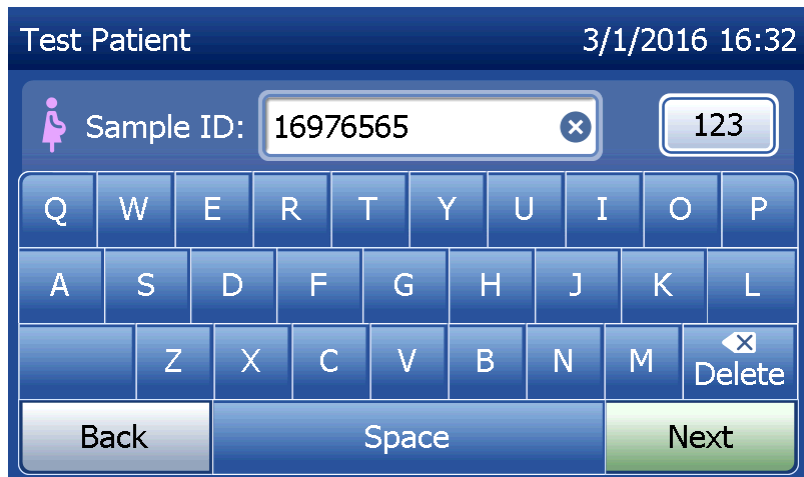
On the touch screen, touching a button name selects it.

For ID fields that require data entry, touch a letter or number key to enter it. The alphabet is always uppercase. To switch from the alphabet keys to the number keys, touch the “**123**” button near the top of the screen. To switch from the number keys to the alphabet keys, touch the “**ABC**” button. Touch the “**Alt**” button, if it is available in your language, to access additional characters. Use the **Delete** key to delete one character. Use the **Space** key to enter a space in the position of the cursor.

To clear the entire ID field, touch the “x” to the right of the ID field area.

The optional barcode scanner can also be used to enter data into fields.

To see an entry that is longer than the ID field area or to edit an entry, touch the ID field area. To edit an entry, use the alphabet, number, or **Delete** keys.



Help button

The **Help** button provides information about the data entry. Press **Close** to exit the Help and enter the correct data.

Next button

Follow the prompts on the analyzer. Typically, the **Next** button confirms an entry in a data entry field and advances to the next part of the sequence. The **Next** button is green only when the analyzer is ready to move to the next part of the sequence.

Back button

Touch **Back** to return to the previous screen, unless otherwise specified.

The screenshot shows a data entry interface for a 'Test Patient' on '3/1/2016 16:31'. The main input field is labeled 'Cassette Lot:' and contains the text 'F1067'. To the left of this field is a small blue box with the word 'LOT' in white. To the right of the input field is a small blue square with a white 'x' icon. Further right is a 'Help' button. Below the input field is a numeric keypad with buttons for digits 1-0. Below the numeric keypad is an alphanumeric keypad with buttons for letters A-G, H-M, and a 'Delete' button with a white 'x' icon. At the bottom of the screen are three large buttons: 'Back' (grey), 'Space' (blue), and 'Next' (green).

Field	Length	Required Format
User	Up to 15 characters	Any combination of letters and numbers. An entry must be made.
Sample ID	Up to 16 characters	Any combination of letters and numbers. An entry must be made.
Cassette Lot Number	5 characters	ANNNN where A=Alpha, N=Number. Enter the lot number exactly as it appears on the cassette pouch. The alphabet is limited on this screen to letters used in cassette lot numbers. An entry must be made.
Calibration Code	10 characters	Enter the cal code exactly as it appears on the cassette box.
Liquid Control Lot Number	Up to 12 characters	Enter the liquid control lot number exactly as it appears on the bottle, or scan the lot number barcodes on the control kit box. An entry must be made.
QCette ID	6 characters	Enter the QCette serial number exactly as it appears on the QCette. An entry must be made.

The analyzer displays an error and beeps if the wrong format is entered or if an invalid code is entered. Press **Close** to dismiss the error and enter the correct data.

Scrolling through data records

Use the up or down arrow when scrolling through data records in longer reports, such as Monthly Usage.

Print

Press **Print** to print a data record.

This print function is only active when a data record is on the display screen.

Cancel button

A **Cancel** button is available in some cases to stop a sequence and return to the previous screen.

Main Menu

Touch the **Main Menu** button to return to the Main Menu.

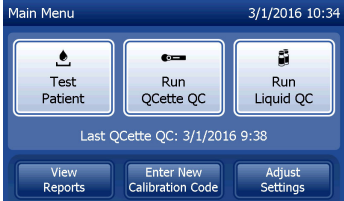



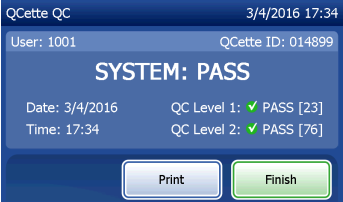
Monthly Usage 3/1/2016 16:43
Analyzer ID: 0000000014

Month	Valid	Invalid	Total
Mar 2016	1	0	1
Feb 2016	15	0	15
Jan 2016	0	0	0
Dec 2015	0	0	0

Back Print Main Menu

Run QCette QC — Quick Reference

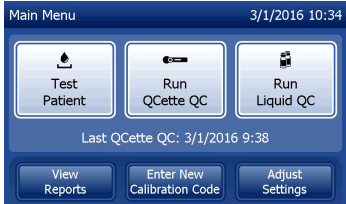




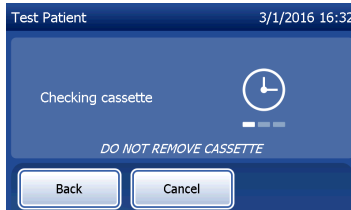
Run QCette QC should be performed at least once every 24 hours. Note that the Main Menu displays the date and time of the last performance of this check.

<p>From the Main Menu select Run QCette QC.</p>	<p>Enter User ID and press Next.</p>	
 <p>Main Menu 3/1/2016 10:34</p> <p>Test Patient Run QCette QC Run Liquid QC</p> <p>Last QCette QC: 3/1/2016 9:38</p> <p>View Reports Enter New Calibration Code Adjust Settings</p>	 <p>QCette QC 3/4/2016 17:30</p> <p>User: 1001 123</p> <p>Q W E R T Y U I O P A S D F G H J K L Z X C V B N M Delete</p> <p>Back Space Next</p>	
<p>Enter the QCette ID, or verify, if it is already entered. Press Next.</p>	<p>Insert QCette and press Next.</p>	<p>Results will be displayed and printed in 3 minutes.</p>
 <p>QCette QC 3/4/2016 17:30</p> <p>QCette ID: 014899</p> <p>1 2 3 4 5 6 7 8 9 0 Delete</p> <p>Back Space Next</p>	 <p>QCette QC 3/4/2016 17:31</p> <p>Insert the QCette and press Next</p> <p>Back Cancel Next</p>	 <p>QCette QC 3/4/2016 17:34</p> <p>User: 1001 QCette ID: 014899</p> <p>SYSTEM: PASS</p> <p>Date: 3/4/2016 QC Level 1: ✓ PASS [23] Time: 17:34 QC Level 2: ✓ PASS [76]</p> <p>Print Finish</p>

If the QCette does not pass, see Section 7 — Troubleshooting, Item 9.

Test Patient – Quick Reference

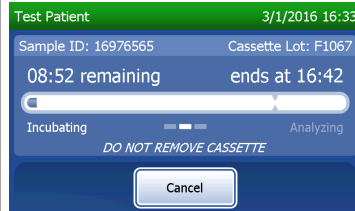
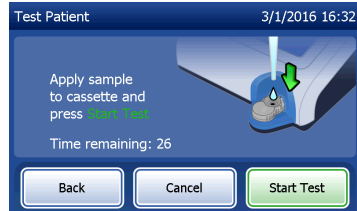
Be sure to prepare the specimen sample according to your specific protocols.

<p>From the Main Menu select Test Patient.</p>	<p>Enter User ID and press Next.</p>	<p>Enter the cassette lot number (on cassette pouch) and press Next.</p>
		
<p>Enter the patient accession number and press Next.</p>	<p>Remove the patient cassette from its pouch. Insert the cassette into the analyzer and press Next.</p>	<p>The analyzer will check that a Rapid fFN 10Q Cassette is properly inserted.</p>
		

The instrument will beep repeatedly and the display will read, “Apply sample to cassette and press Start Test.” Add 200 µL of patient sample and press **Start Test**.

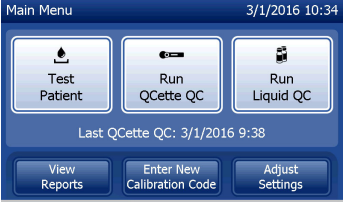
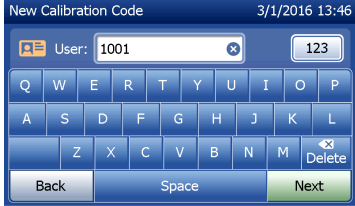


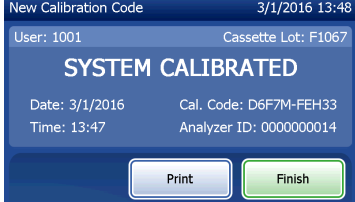
The analyzer will begin a 10-minute countdown, with 7 minutes of incubation and 2–3 minutes of analysis of the cassette.

When testing is complete, the system will display and print the result.



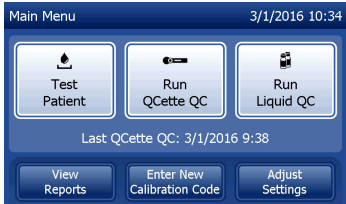





Enter New Calibration Code – Quick Reference

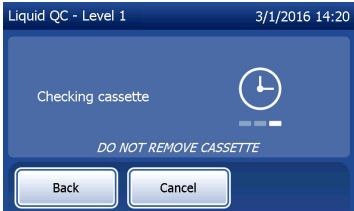
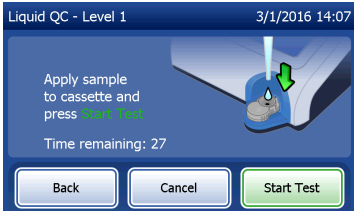
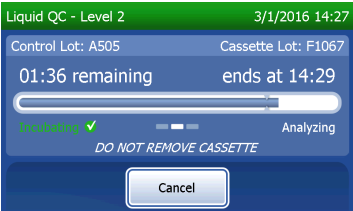


Calibration must be set when changing cassette lots.

<p>From the Main Menu, select Enter New Calibration Code.</p>	<p>Enter User ID and press Next.</p>	<p>Enter the cassette lot number (on cassette pouch) and press Next.</p>
 <p>Main Menu 3/1/2016 10:34</p> <p>Test Patient Run QCette QC Run Liquid QC</p> <p>Last QCette QC: 3/1/2016 9:38</p> <p>View Reports Enter New Calibration Code Adjust Settings</p>	 <p>New Calibration Code 3/1/2016 13:46</p> <p>User: 1001 123</p> <p>Q W E R T Y U I O P A S D F G H J K L Z X C V B N M Delete</p> <p>Back Space Next</p>	 <p>New Calibration Code 3/1/2016 13:46</p> <p>LOT Cassette Lot: F1067 Help</p> <p>1 2 3 4 5 6 7 8 9 0 A B C D E F G H J K L M Delete</p> <p>Back Space Next</p>
<p>Enter the Calibration Code (on the cassette box) and press Next.</p>	<p>Calibration results will be displayed and can be printed. Press Finish to return to the Main Menu.</p>	
 <p>New Calibration Code 3/1/2016 13:47</p> <p>CAL Cal. Code: D6F7M-FEH33 123</p> <p>Q W E R T Y U I O P A S D F G H J K L Z X C V B N M Delete</p> <p>Back Space Next</p>	 <p>New Calibration Code 3/1/2016 13:48</p> <p>User: 1001 Cassette Lot: F1067</p> <p>SYSTEM CALIBRATED</p> <p>Date: 3/1/2016 Cal. Code: D6F7M-FEH33 Time: 13:47 Analyzer ID: 0000000014</p> <p>Print Finish</p>	

Run Liquid QC — Quick Reference

Run Liquid Controls with every cassette lot change.

<p>From the Main Menu, select Run Liquid QC.</p>	<p>Enter the User ID and press Next.</p>	<p>Enter the Cassette Lot number (on cassette pouch) and press Next.</p>
 <p>Main Menu 3/1/2016 10:34</p> <p>Test Patient Run QCette QC Run Liquid QC</p> <p>Last QCette QC: 3/1/2016 9:38</p> <p>View Reports Enter New Calibration Code Adjust Settings</p>	 <p>Liquid QC 3/1/2016 14:03</p> <p>User: 1001 123</p> <p>Q W E R T Y U I O P A S D F G H J K L Z X C V B N M Delete</p> <p>Back Space Next</p>	 <p>Liquid QC 3/1/2016 14:04</p> <p>LOT Cassette Lot: F1067 Help</p> <p>1 2 3 4 5 6 7 8 9 0 A B C D E F G H J K L M Delete</p> <p>Back Space Next</p>
<p>Select Level 1 or Level 2 and press Next.</p>	<p>Enter the Control Lot number (on bottle label and controls' box) and press Next.</p>	<p>Insert cassette and press Next.</p>
 <p>Liquid QC 3/1/2016 14:05</p> <p>Level 1 Level 2</p> <p>Back Cancel Next</p>	 <p>Liquid QC - Level 1 3/1/2016 14:05</p> <p>LOT Control Lot: AS054 ABC</p> <p>1 2 3 4 5 6 7 8 9 0 A B C D E F G H J K L M Delete</p> <p>Back Space Next</p>	 <p>Liquid QC - Level 1 3/1/2016 14:07</p> <p>Insert the cassette and press Next.</p> <p>Back Cancel Next</p>

<p>The analyzer will check that a Rapid fFN 10Q cassette is properly inserted.</p>	<p>The instrument will beep repeatedly and the display will read, “Add sample to cassette and press Start Test.” Add 200 µL of control sample and press Start Test.</p>	<p>The analyzer will begin a 10-minute countdown, with 7 minutes of incubation and 2–3 minutes of analysis of the cassette.</p>
		
<p>When testing is complete, the system will display and print the result. Select Finish to run the next control sample.</p>	<p>Note: Both a Level 1 and a Level 2 control sample must be run.</p>	<p>Repeat the test with the other control sample and a fresh cassette.</p>
		

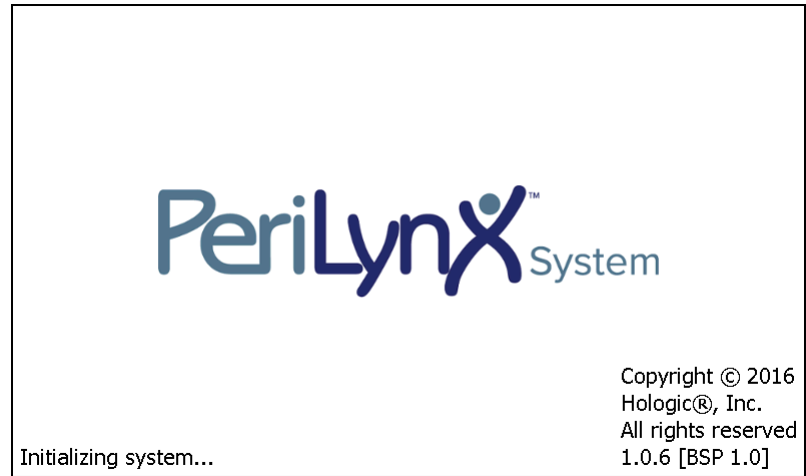
If the liquid control result does not pass, refer to Section 7 – Troubleshooting, Item 10.

Section 4 — Software Functions — Detailed Descriptions

Startup Screen

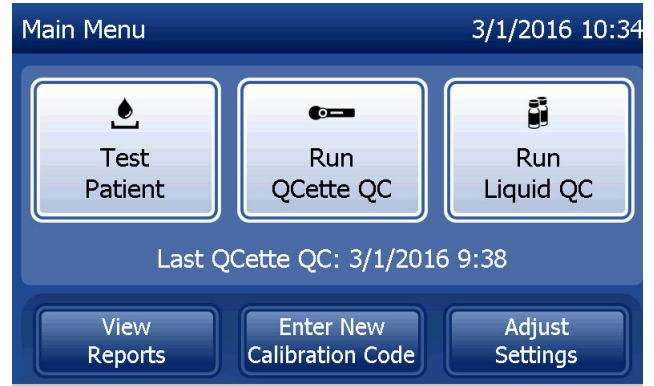
Upon power up, the analyzer displays the Hologic logo and then PeriLynx system logo with the message “Initializing system...” for 60 seconds. Then the analyzer performs a self-test of the analyzer components. This screen also displays the software version.

Once the self-test is complete, the display will change to the Main Menu.

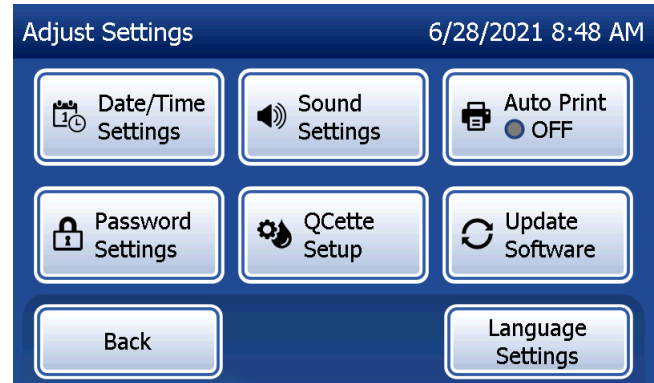


Main Menu

The Main Menu consists of Test Patient, Run QCette QC, Run Liquid QC, View Reports, Enter New Calibration Code, and Adjust Settings.



For View Reports and Adjust Settings, selecting the button displays a submenu.

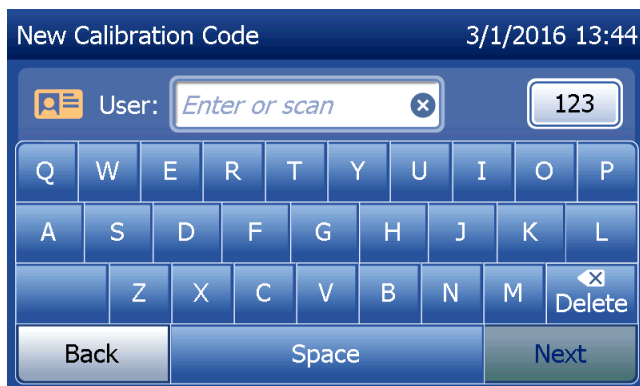


Enter New Calibration Code

Select **Enter New Calibration Code** on the Main Menu screen to set the calibration on the analyzer. Follow the analyzer prompts. Calibration must be set when changing cassette lots.

Note: If the calibration has not been set, Test Patient and Run Liquid QC cannot be run. Calibration must be set before the analyzer can be used for testing.

The User ID must be entered to proceed to the next step. Press **Next** to accept the ID. This field will accept 15 alphanumeric characters.



The Cassette Lot number must be entered to proceed to the next step. The Cassette Lot is located on the cassette pouch and the cassette box. The software requires that the lot number is entered in the correct format: one alpha character followed by four numeric characters (e.g., F1067).

The screenshot shows a software interface titled "New Calibration Code" with a timestamp of "3/1/2016 13:46". Below the title, there is a label "LOT" in a blue box followed by "Cassette Lot:" and a text input field containing "F1067". To the right of the input field is a small "x" icon and a "Help" button. Below this is a numeric keypad with digits 1-0, an alpha keypad with letters A-M, and a "Delete" button with an "x" icon. At the bottom, there are three buttons: "Back", "Space", and "Next".

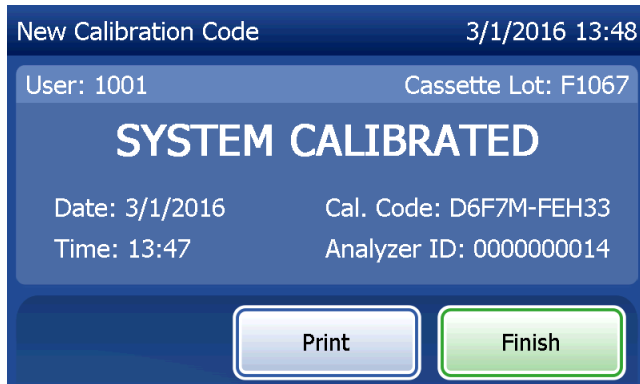
The Calibration Code (Cal. Code) must be entered to proceed to the next step. The calibration code is located on the cassette box. The software requires that the code number is entered in the correct format: 10 alphanumeric characters with a dash in the middle. Enter the calibration code exactly as it is given on the box.

The screenshot shows a software interface titled "New Calibration Code" with a timestamp of "3/1/2016 13:47". Below the title, there is a label "CAL" in a blue box followed by "Cal. Code:" and a text input field containing "D6F7M-FEH33". To the right of the input field is a small "x" icon and a "123" button. Below this is a full alphanumeric keypad with letters Q-Z, a "Delete" button with an "x" icon, and "Back", "Space", and "Next" buttons at the bottom.

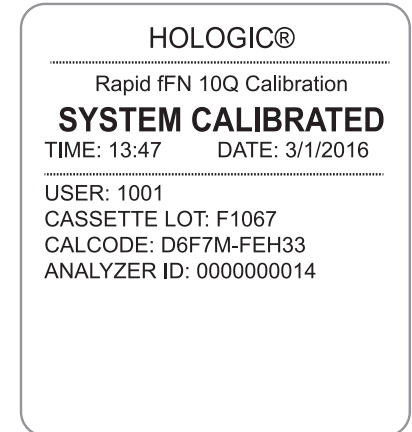
Note: The calibration code is established by Hologic for each lot of Rapid fFN 10Q Cassettes.

Calibration data record

The complete record will be printed automatically if Auto Print is set to ON, or it may be printed/reprinted by pressing the **Print** button.

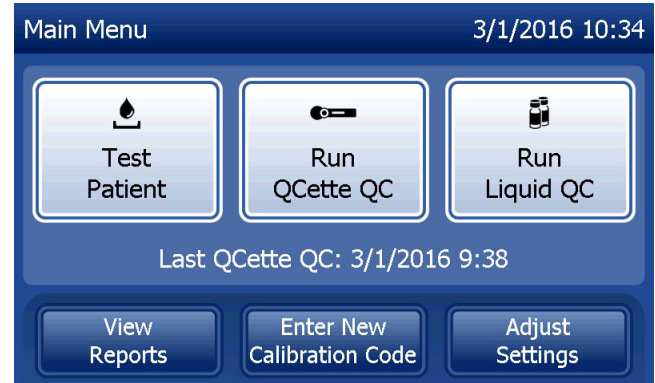


Display and Printout



Test Patient

Select **Test Patient** on the Main Menu to test a patient sample. Follow the analyzer prompts.



The User ID must be entered to proceed to the next step. Press **Next** to accept the ID. This field will accept 15 alphanumeric characters.



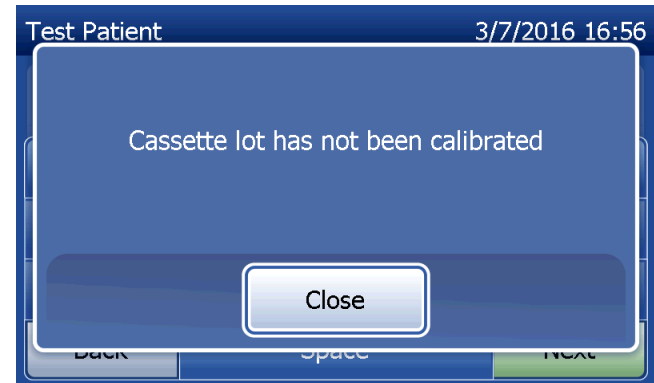
The Cassette Lot number must be entered to proceed to the next step. The Cassette Lot is located on the cassette pouch and the cassette box. The software requires that the lot number is entered in the correct format: one alpha character followed by four numeric characters (e.g., F1067).

It is important to use the cassette lot number on each cassette's pouch or box.

The analyzer automatically compares the cassette lot number used to set calibration with the cassette lot number used for patient testing. The analyzer accepts cassettes from any of the last five cassette lots for which calibration has been set.

If the cassette lot numbers do not match, the test process cannot continue. When this occurs, the display says that the cassette lot has not been calibrated. Press **Close** and the cassette lot number used for calibration will be displayed.

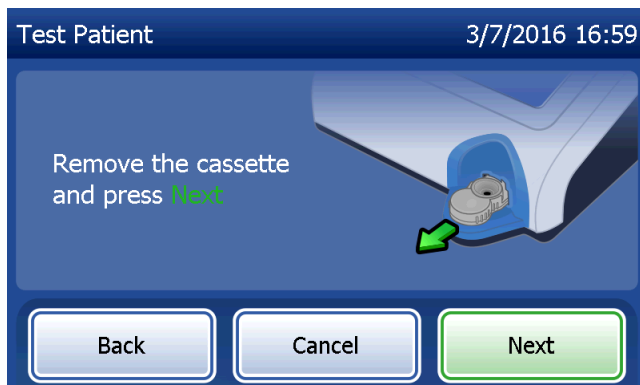
Note: If the cassette lot number has changed, Enter New Calibration Code must be performed.



Enter up to 16 alphanumeric characters for a Sample ID and press **Next**. The Sample ID must be entered to proceed to the next step.

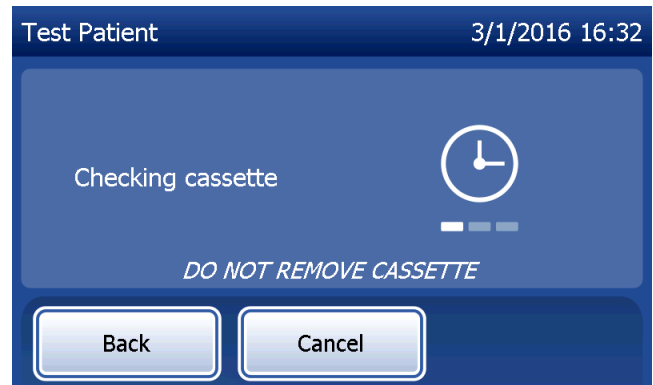
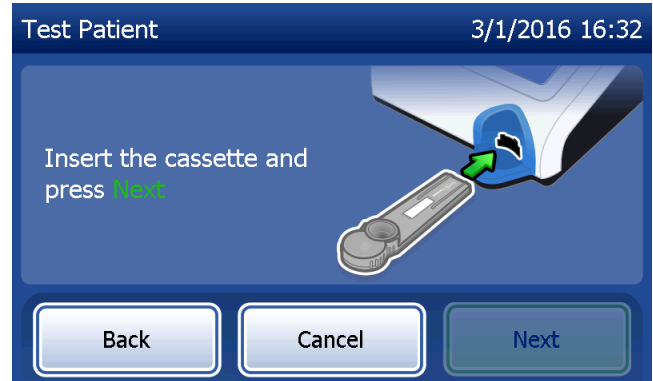


This message will be displayed if a cassette is present in the analyzer prior to reaching the next screen. Remove cassette and press **Next**.

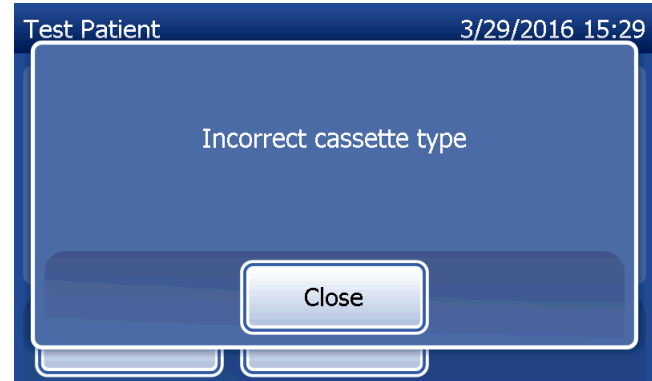


The analyzer then prompts the user to insert cassette and press **Next**.

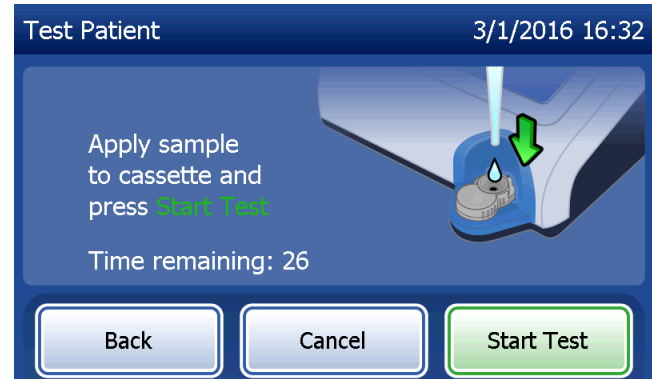
The analyzer will check that a Rapid fFN 10Q cassette is properly inserted.



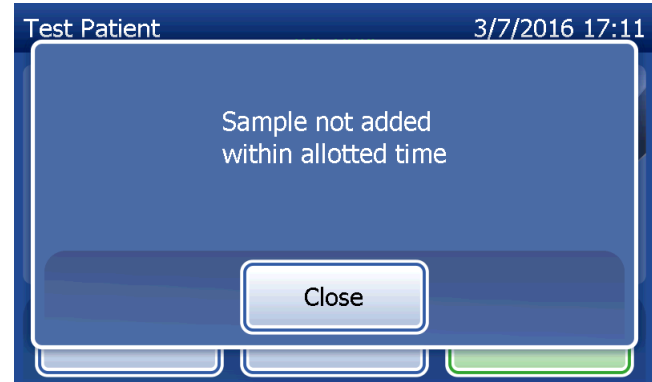
If the wrong kind of cassette is inserted, the test cannot proceed. Press **Close** and remove the incorrect cassette.



A 30-second timer starts during which time the analyzer beeps. Add 200 μ L of patient sample and immediately press Start Test.

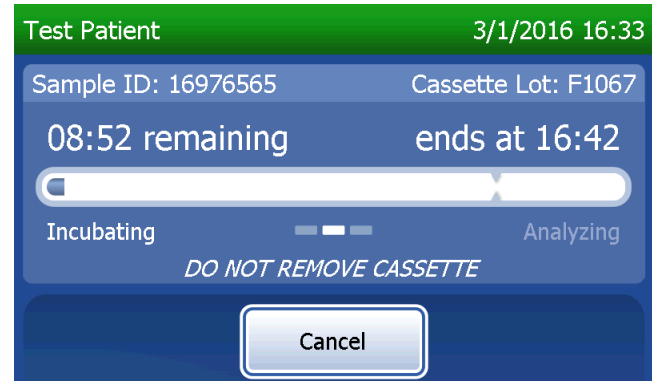


If the patient sample is not added and **Start Test** is not pressed within allotted time, the test process cannot continue. The display says that the sample was not added in time. Press **Close**, remove the cassette, and press **Finish** to return to the Main Menu. No record of the test will be held in memory.



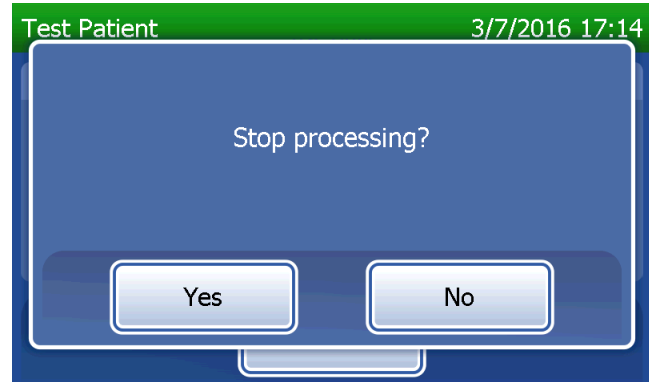
Once the sample is added, the analyzer will begin a 10-minute countdown.

To abort the test, press **Cancel**. Pressing **Cancel** and then confirming that you want to stop the process will terminate the test and the data will be lost.



Upon completion of the 7-minute incubation period, the analyzer will begin the analysis of the cassette. Do not disturb the analyzer until the results are displayed. The analysis will take approximately 2–3 minutes.

This message will be displayed if **Cancel** was pressed during testing. Select **Yes** to stop processing or **No** to continue the test. This message will hold for 5 seconds and then continues the test. If the test is cancelled, remove the cassette and press **Finish**. A new cassette will be required to repeat the test.



Patient data record

The patient test results are displayed. The complete record will be printed automatically if Auto Print is set to ON, or it may be printed/reprinted by pressing the **Print** button.

Test Patient 3/1/2016 16:42

Sample ID: 16976565 Cassette Lot: F1067

fFN CONC: 160 ng/mL

Date: 3/1/2016
Time: 16:42

Internal Controls
Analyzer QC: PASS
Cassette QC: PASS

Print Finish

Display and Printout

HOLOGIC®

Rapid fFN 10Q Test Result

fFN CONC: 160 ng/mL

TIME: 16:42 DATE: 3/1/2016

SAMPLE: 16976565
USER: 1001
CASSETTE LOT: F1067
CALCODE: D6F7M-FEH33
ANALYZER ID: 0000000014

INTERNAL CONTROLS
ANALYZER QC: PASS
CASSETTE QC: PASS

Patient results are displayed as the fFN concentration in ng/mL, or INVALID.

An INVALID result should be repeated. (See Section 7 — Troubleshooting, Item 12.)

Note: Internal Controls are performed automatically during each Rapid fFN test. These internal controls check for

- (1) a threshold level of signal at the procedural control line,
- (2) proper sample flow across the Rapid fFN 10Q cassette,
- (3) absence of conjugate aggregation, and
- (4) proper functioning of the PeriLynx analyzer hardware.

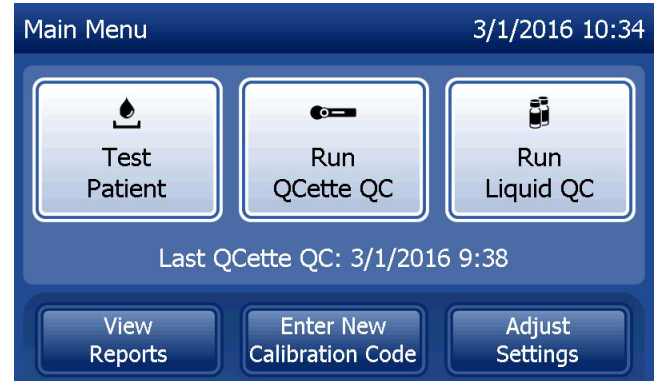
Run QCette QC

Prior to running the PeriLynx QCette® for the first time, QCette Setup must be performed. See Adjust Settings — QCette Setup. Refer to the PeriLynx QCette directional insert for more information.

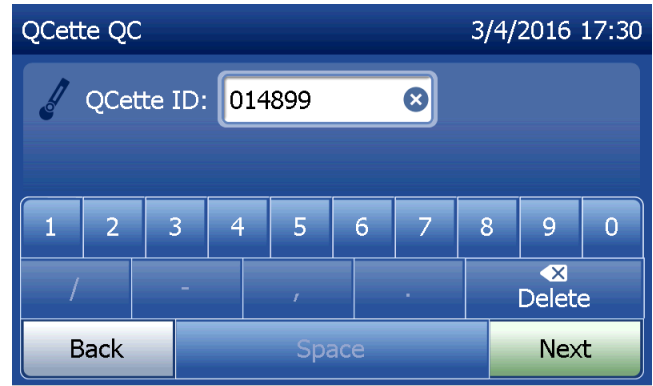
Run QCette QC should be performed at least once every 24 hours. Note that Main Menu shows the date and time of the Last QCette QC.

From the Main Menu, select **Run QCette QC**.

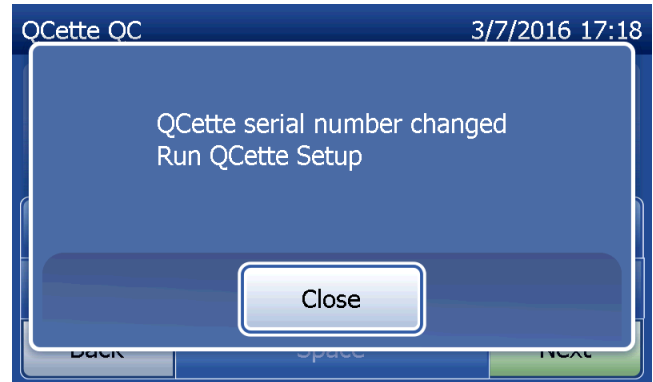
The User ID must be entered to proceed to the next step. Press **Next** to accept the ID. This field will accept 15 alphanumeric characters.



The QCette ID is displayed. (It was originally entered during QCette setup.) The QCette ID is the serial number for the QCette. Confirm that the serial number displayed matches the serial number printed on the QCette plastic housing and press **Next**. The software requires that the serial number is entered in the correct format: six numeric characters (e.g., 014899). Enter all leading zeros.



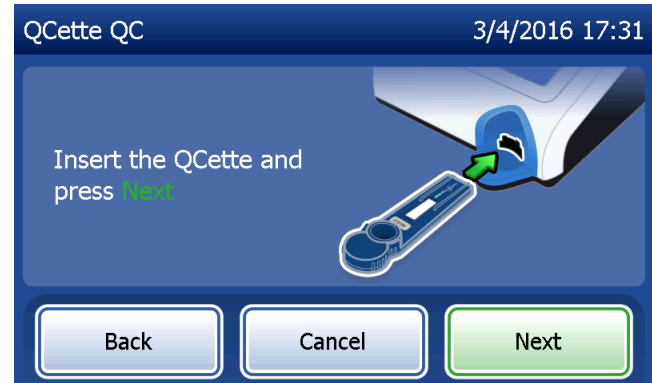
This message will be displayed if the QCette serial number entered is not identical to the serial number entered at the time of QCette setup. Press **Close**. Either set up a new QCette, or re-do Run QCette QC with the correct QCette.



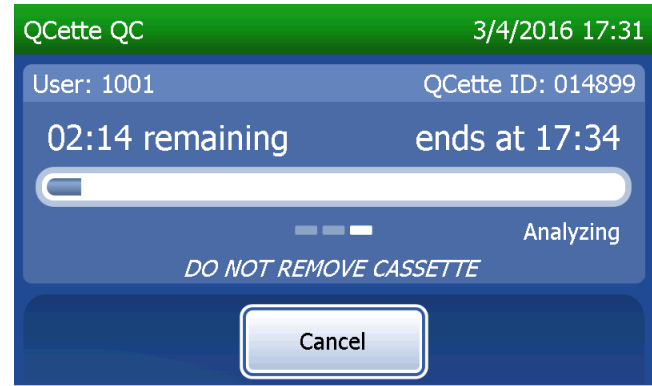
This screen will be displayed if a cassette is present in the analyzer prior to reaching the next screen. Remove cassette and press **Next**.



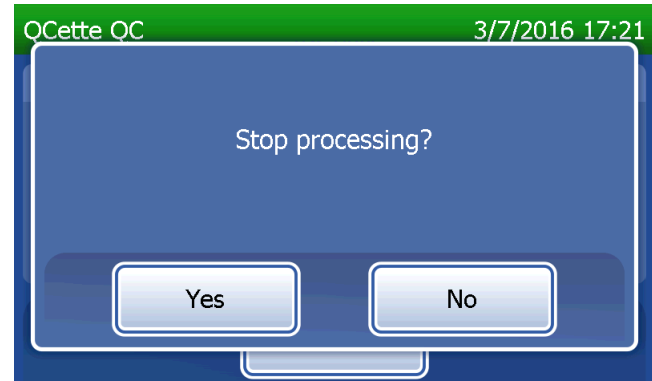
The analyzer then prompts the user to insert the QCette and press **Next**.



The analyzer will read the QCette. Do not disturb the analyzer until the results are displayed. The analysis will take approximately 2–3 minutes.



This message will be displayed if **Cancel** was pressed during testing. Select **Yes** to stop processing or **No** to continue the test. This message will hold for 5 seconds and then continues the test. If the test is cancelled, remove the cassette and press **Finish test**.



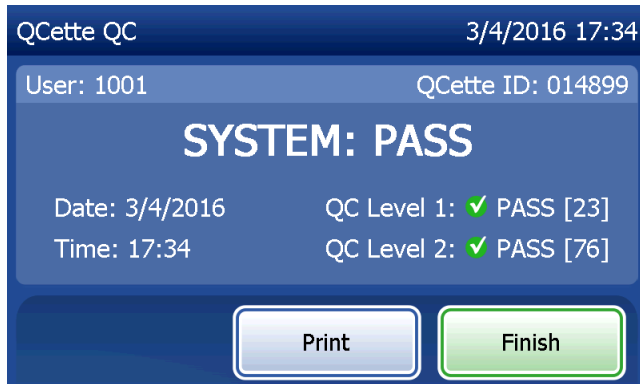
QCette data record

The complete record will be printed automatically if Auto Print is set to ON, or it may be printed/reprinted by pressing the **Print** button.

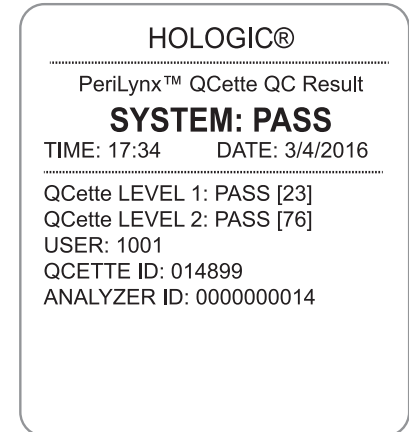
QCette results are SYSTEM: PASS or SYSTEM: FAIL. The analyzer displays the PASS or FAIL result and the result for each QCette level (Level 1 and Level 2).

A FAIL result should be repeated. (See Section 7 — Troubleshooting, Items 8 and 9.)

Press **Finish** to return to the Main Menu.

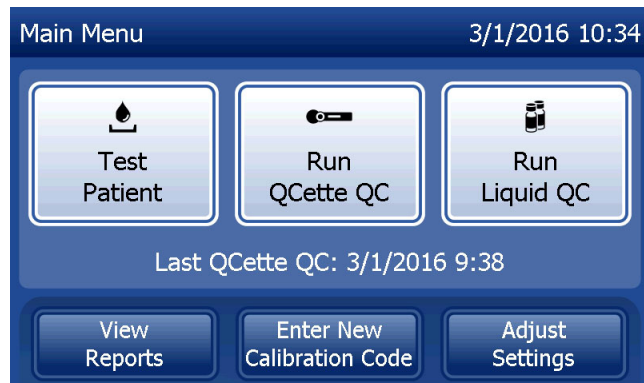


Display and Printout



Liquid Controls

On the Main Menu, select **Run Liquid QC** to run the liquid controls.



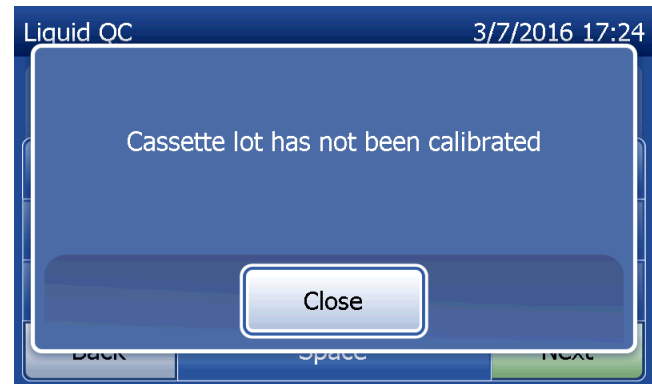
The User ID must be entered to proceed to the next step. Press **Next** to accept the ID. This field will accept 15 alphanumeric characters.



The Cassette Lot number must be entered to proceed to the next step. The Cassette Lot is located on the cassette pouch and the cassette box. The software requires that the lot number is entered in the correct format: one alpha character followed by four numeric characters (e.g., F1067).

The analyzer automatically compares the Cassette Lot number used to set calibration with the cassette lot number used for testing controls.

If the cassette lot numbers do not match, the test process cannot continue. When this occurs, the display says that the cassette lot has not been calibrated. Press **Close** and the cassette lot number used for calibration will be displayed.



Select **Level 1** control or **Level 2** control.



Enter the control lot number and press **Next**. This field will accept up to 12 alphanumeric characters.



This message will be displayed if a cassette is present in the analyzer prior to reaching the next screen. Remove cassette and press **Next**.

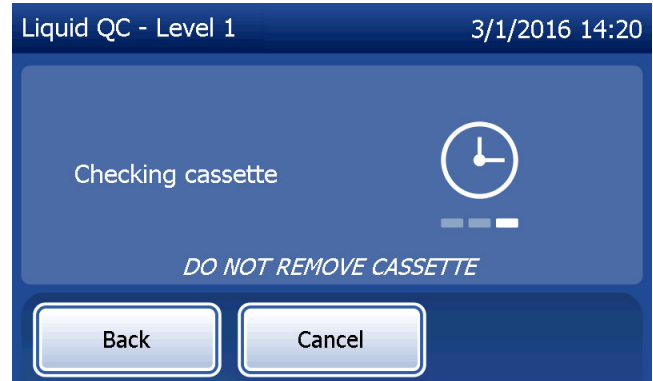


The analyzer then prompts the user to insert the cassette and press **Next**.

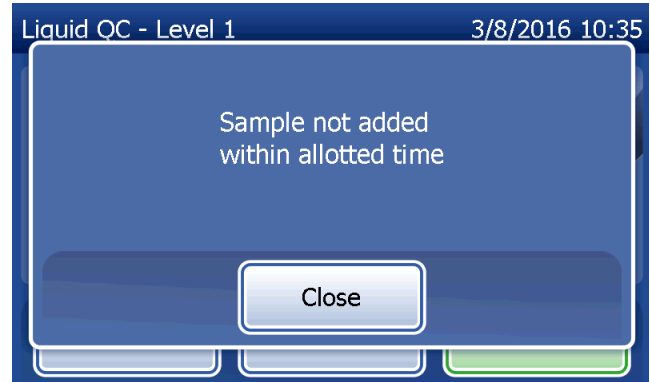


The analyzer will check that a Rapid fFN 10Q Cassette is properly inserted.

A 30-second timer starts during which time the analyzer beeps. Add 200 μ L of control sample and immediately press **Start Test**.

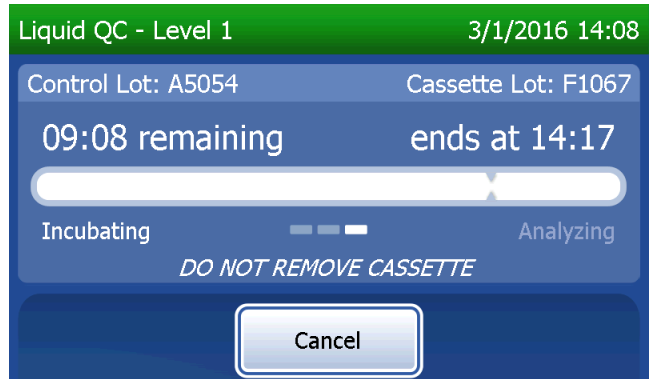


If the liquid control sample is not added and **Start Test** is not pressed within allotted time, the test process cannot continue. The display says that the sample was not added in time. Press **Close**, remove the cassette, and press **Finish** to return to the Main Menu. No record of the test will be held in memory.



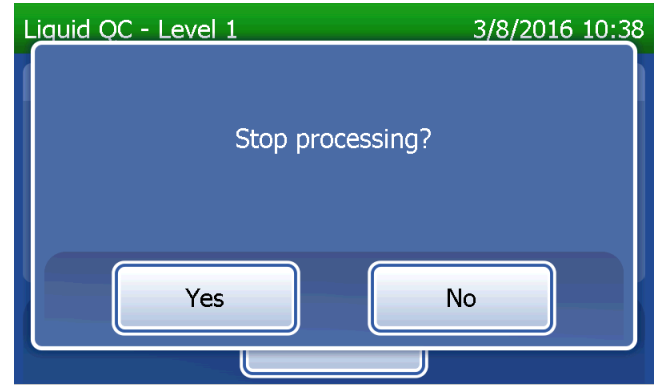
Once the sample is added, the analyzer will begin a 10-minute countdown.

To abort the test, press **Cancel**. Pressing **Cancel** and then confirming that you want to stop the process will terminate the test and the data will be lost.



Upon completion of the 7-minute incubation period, the analyzer will begin the analysis of the cassette. Do not disturb the analyzer until the results are displayed. The analysis will take approximately 2–3 minutes.

This message will be displayed if **Cancel** was pressed during testing. Select **Yes** to stop processing or **No** to continue the test. This message will hold for 5 seconds and then continues the test. If the test is cancelled, remove the cassette and press **Finish test**. If the test is cancelled, a new cassette will be required to repeat the test.



Liquid control data record

The complete record will be printed automatically if Auto Print is set to ON, or it may be printed/reprinted by pressing the **Print** button.

Control results are displayed as the fFN concentration in ng/mL or as INVALID. Refer to the Rapid fFN Control Kit directional insert for acceptable results for the liquid controls.

An out-of-range result or an INVALID result should be repeated. (See Section 7 — Troubleshooting, Items 10 and 11.)

The screenshot shows a dark blue interface with white text. At the top, it reads "Liquid QC - Level 2" on the left and "3/1/2016 14:29" on the right. Below this, "Control Lot: A5053" and "Cassette Lot: F1067" are displayed. The central focus is "fFN CONC: 112 ng/mL" in large white font. To the left, the date "Date: 3/1/2016" and time "Time: 14:29" are shown. To the right, an "Internal Controls" box contains "Analyzer QC: ✓ PASS" and "Cassette QC: ✓ PASS". At the bottom, there are two buttons: "Print" (white with blue border) and "Finish" (green with white border).

Display and Printout

The printout is enclosed in a rounded rectangle and contains the following text:
HOLOGIC®

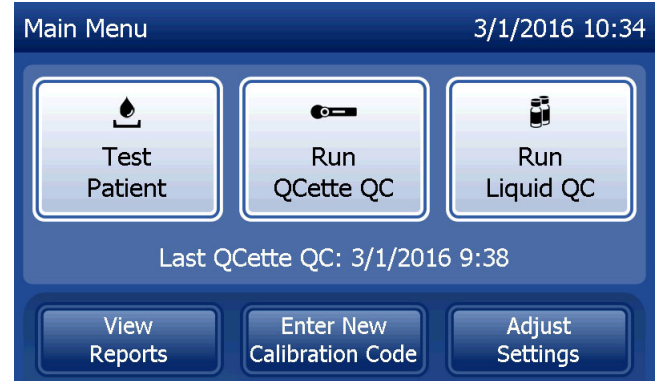
Rapid fFN 10Q Liquid QC Result
fFN CONC: 112 ng/mL
TIME: 14:29 DATE: 3/1/2016

LIQUID CONTROL: LEVEL 2
CTRL LOT: A5053
USER: 1001
CASSETTE LOT: F1067
CAL CODE: D67F7M-FEH33
ANALYZER ID: 0000000014

INTERNAL CONTROLS
ANALYZER QC: PASS
CASSETTE QC: PASS

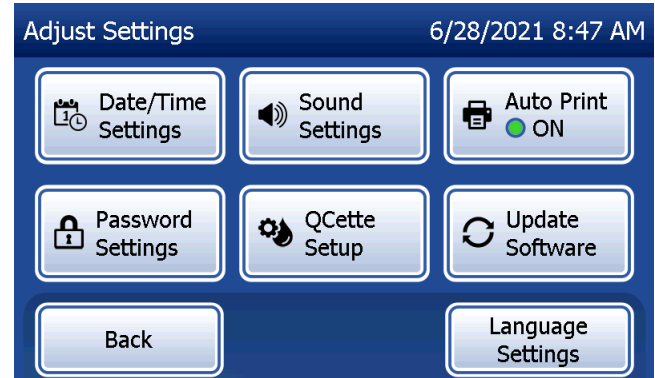
Adjust Settings

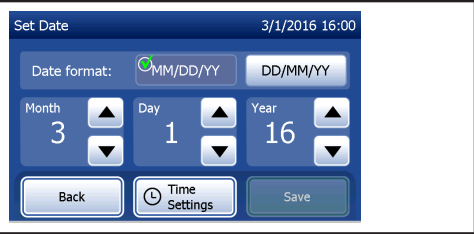
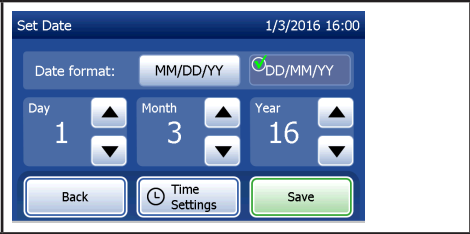
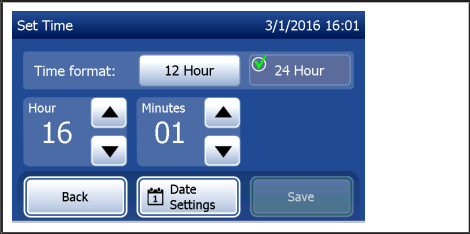
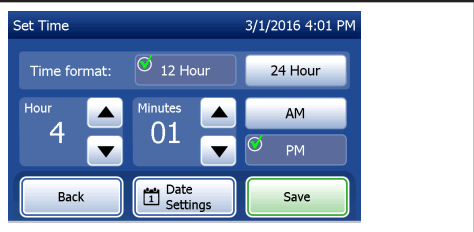
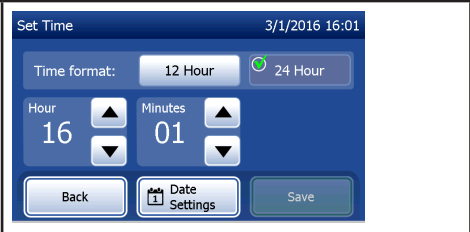
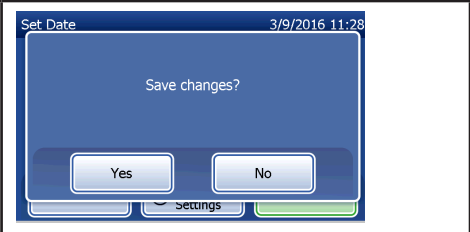
The **Adjust Settings** button on the Main Menu screen allows the user to change the Date/Time, adjust the Sound Settings, Auto Print, change the Password Settings or to perform QCette Setup. This option also allows Hologic Technical Support to update the software version. Press the **Adjust Settings** button on the Main Menu to access the Adjust Settings screen.



Adjust Settings – Date/Time

Select **Date/Time Settings**.

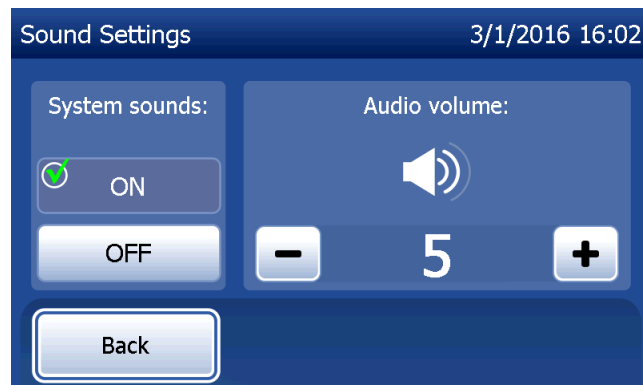
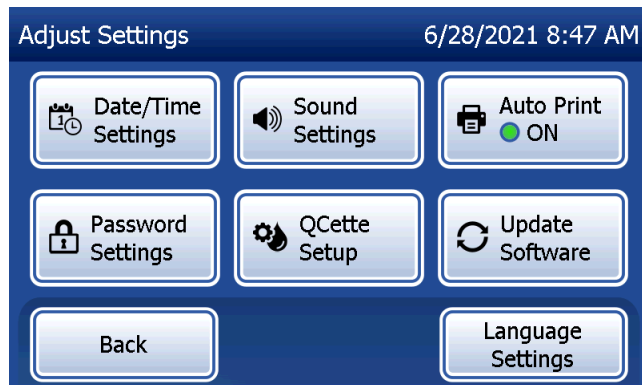


<p>Set the date. In the Date format area, select the preferred format. The green check marks indicates the selection.</p>	<p>Use the up or down arrow to change the date. Press the Save button to accept.</p>	<p>To change the time settings, press the Time Settings button. In the Time format area, select the preferred time format. The green check mark indicates the selection.</p>
		
<p>Use the up or down arrow to change the time. When the time is set in the 12-hour format, choose AM or PM. The green check mark indicates the selection. Press the Save button to accept.</p>	<p>From the Set Time screen, you have the option to return to the Date Settings screen. Or, press the Back button to return to the Adjust Settings screen.</p>	<p>If there are any unsaved changes and the Back button, Date Settings button, or Time Settings button is pressed, a “Save changes” screen is displayed. Press Yes to save changes or No to discard the changes.</p>
		

Adjust Settings – Sound Settings

In the Sound Settings section, select whether the audible tone (beep) will be on or off. A green check mark indicates the selection.

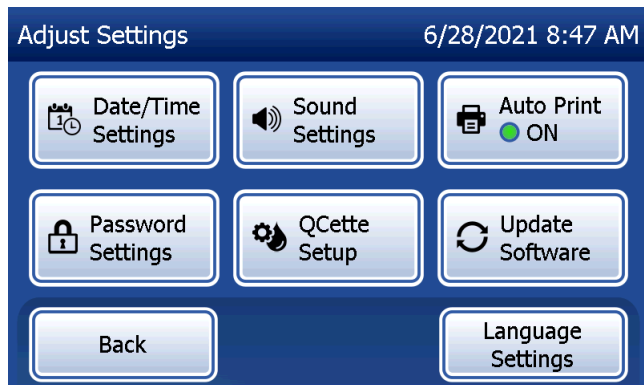
If the sound is turned on, use the plus (+) or minus (-) buttons to increase or decrease the audio volume. If the sound is turned on, touching the plus or minus buttons also makes the analyzer play the sound at that volume. Press the **Back** button to return to the Adjust Settings screen.



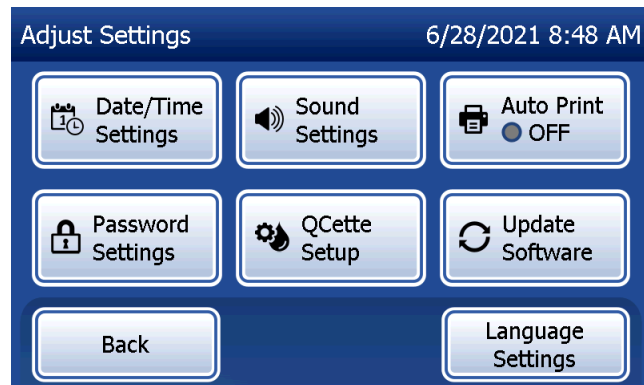
Adjust Settings – Auto Print

On the Adjust Settings screen, press the **Auto Print** button to change whether the Auto Print feature is on or off. A green circle indicates that Auto Print is on.

Auto Print automatically prints test results when set in the ON position. When Auto Print is OFF, results may be printed by pressing the **Print** button.



Auto Print ON



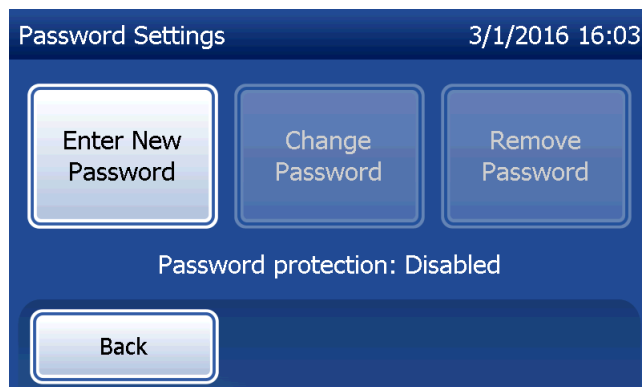
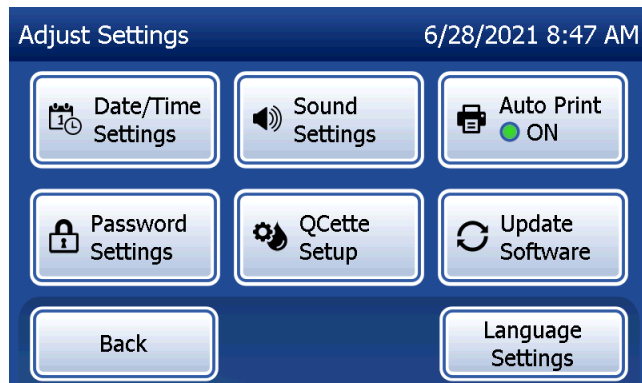
Auto Print OFF

Adjust Settings — Password Settings

The analyzer can be set so that a password is required to view and print patient information in the Access Data section.

If the password protection is disabled, the Access Data features are available to all users.

If the password protection is disabled, to enable the password protection, touch the **Enter New Password** button.



Use the touch screen or the optional barcode scanner to enter the password.

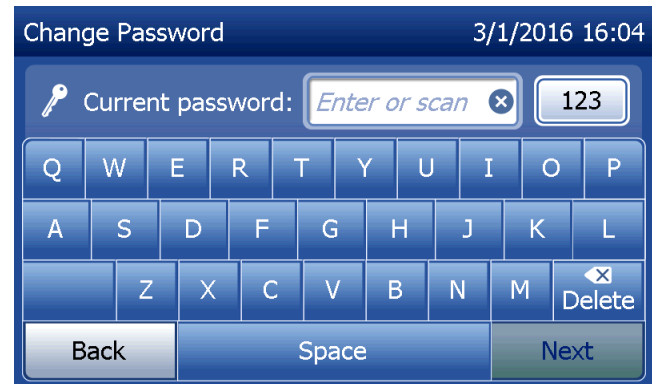
Press the **Save** button.

A password is now required to view or print the information in the Access Data section.



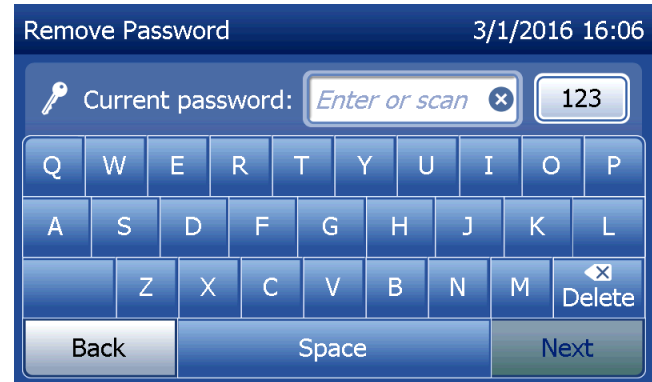
To change the password, press the **Change Password** button. Use the touch screen or the optional barcode scanner to enter the current password. Press the **Next** button, and then enter the new password.

Press the **Save** button.



To remove the password protection, press the **Remove Password** button. Use the touch screen or the optional barcode scanner to enter the current password. Press the **Next** button.

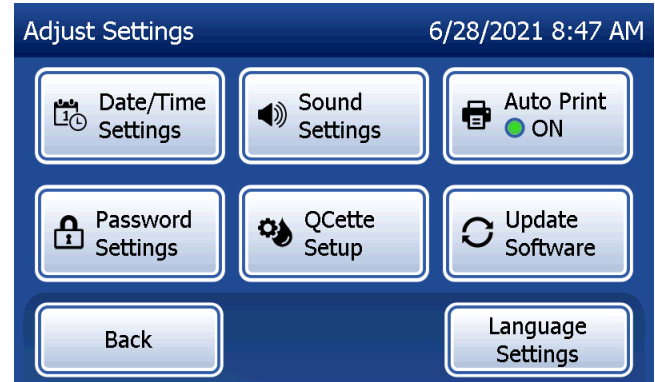
The password protection changes from “Enabled” to “Disabled”. No password is required to view or print the information in the Access Data section.



Adjust Settings – QCette Setup

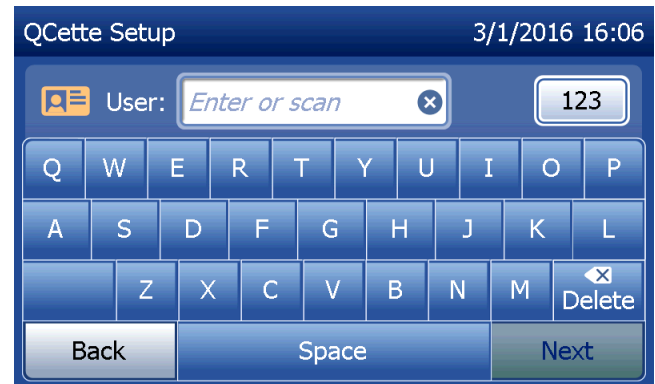
The QCette Setup initializes the QCette for use in evaluating the performance of the analyzer. During the initialization process, the performance criteria of the analyzer are established. QCette Setup must be performed **PRIOR** to running the QCette as an instrument verification device.

From the Main Menu, select **Adjust Settings**.



Select **QCette Setup** on the Adjust Settings menu to begin.

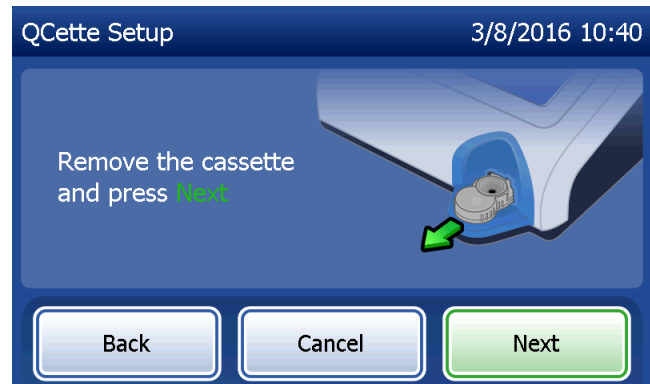
Enter the User ID to proceed to the next step. Press **Next** to accept the ID. This field will accept 15 alpha and/or numeric characters.



The QCette ID must be entered to proceed to the next step. The QCette ID is the serial number for the QCette. The serial number is printed on the QCette plastic housing. The software requires that the serial number is entered in the correct format: six numeric characters (e.g., 014899). Enter all leading zeros.



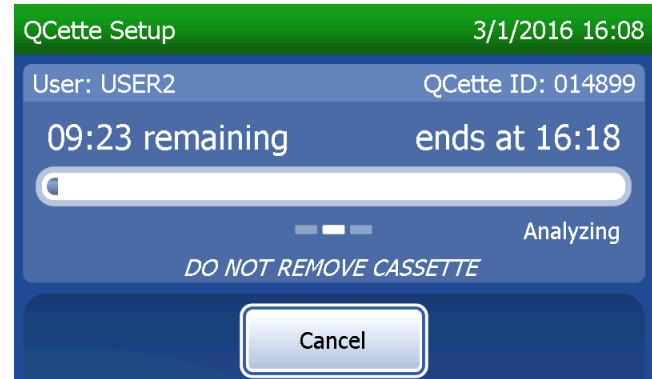
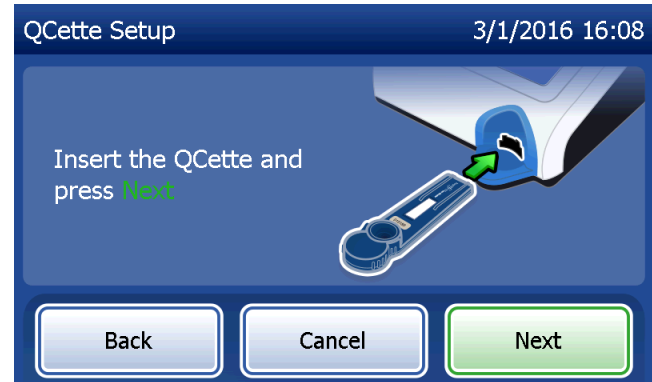
This message will be displayed if a cassette is present in the analyzer prior to reaching the next screen. Remove cassette and press **Next**.



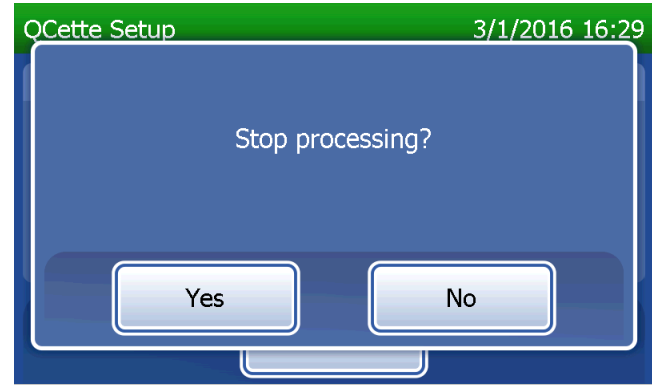
The analyzer then prompts the user to insert the QCette and press **Next**.

A ten-minute timer starts.

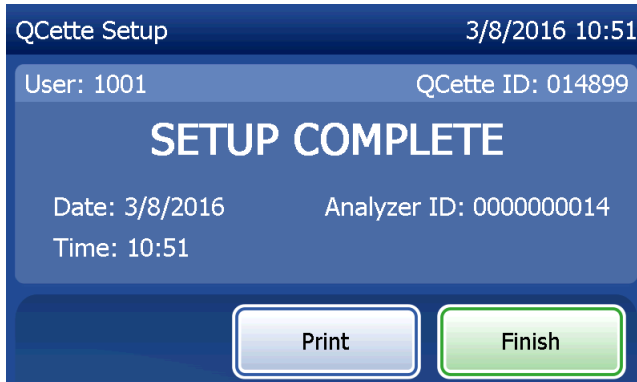
The analyzer will begin initializing the QCette. Do not disturb the analyzer until the results are displayed. The initialization process will take approximately 10 minutes. Initialization can be terminated by pressing **Cancel**.



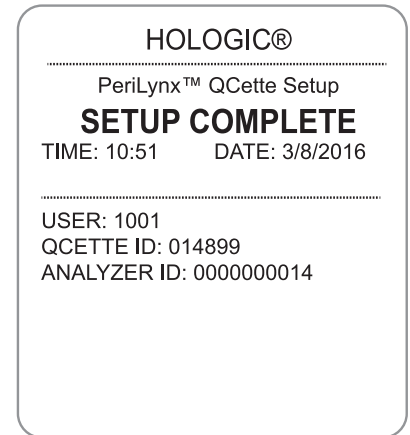
This message will be displayed if **Cancel** was pressed during testing. Select **Yes** to stop processing or **No** to continue the test. This message will hold for 5 seconds and then continues the test. If the test is cancelled, remove the cassette and press **Finish test**.



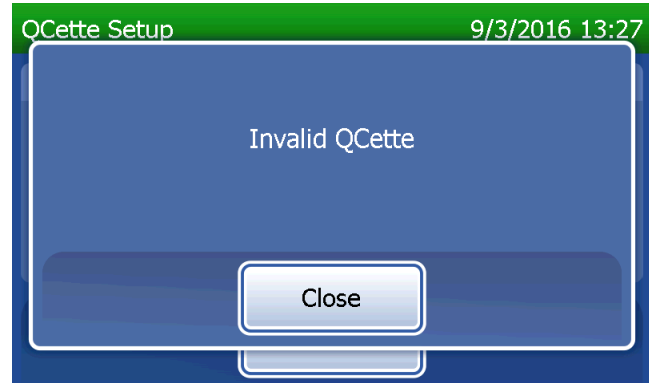
Upon successful completion of the QCette Setup, this message will be displayed. SETUP COMPLETE indicates that the performance criteria of the analyzer have been established. Press **Finish** to return to the Main Menu.



Display and Printout

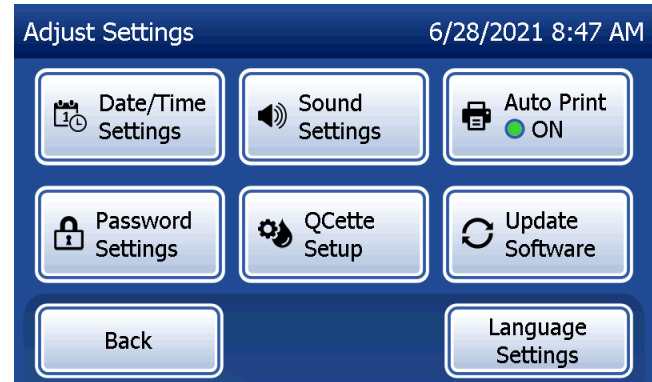


This message will be displayed if the QCette Setup is not completed. It indicates that the performance criteria of the analyzer have not been established. If the QCette setup error occurs, see Section 7 — Troubleshooting, Item 8.



Adjust Settings – Update Software

The Adjust Settings screen has an option which allows the software version to be updated.

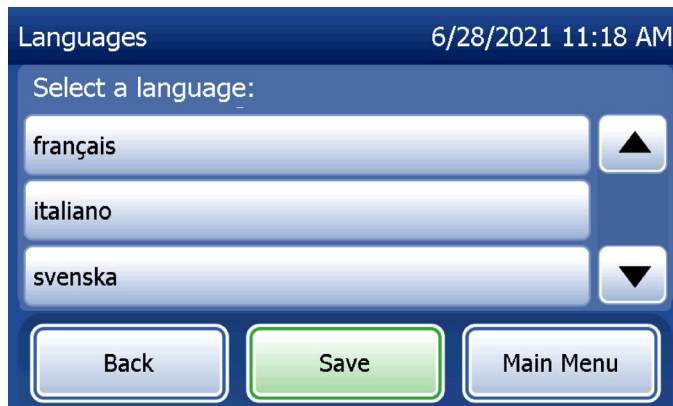


Adjust Settings – Language Settings

The Adjust Settings screen has an option which allows the language displayed on the analyzer's screen display to be changed.

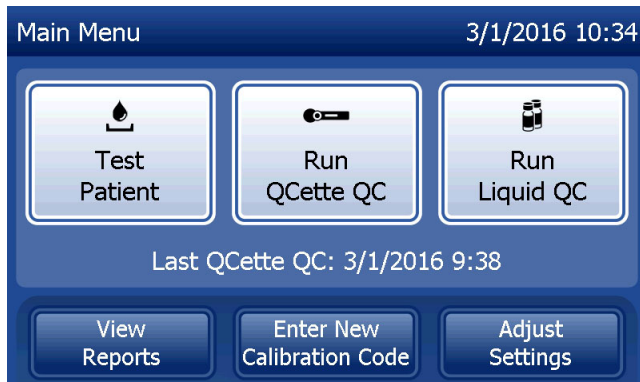
To change the language displayed on the screen display, press the **Language Settings** button. Use the up or down arrow to scroll through the list of languages. Touch the language name to select it.

Press the **Save** button. The analyzer may take approximately 60 seconds to switch languages.



View Reports

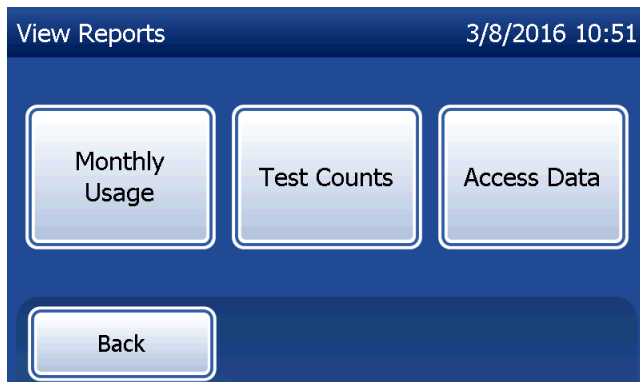
From the Main Menu, the **View Reports** button allows the user to view and print the monthly usage report, the test counts, and the Access Data functions.



Monthly Usage

On the View Reports screen, touch the **Monthly Usage** button to view or print a summary of patient tests performed for each month in the past 12 months (rolling calendar).

Note: to transfer the monthly usage report to a USB device, connect a USB drive to any USB port on the back of the analyzer before you touch the **Monthly Usage** button on the View Reports screen.



Use the up or down arrow to scroll through the report.

The total number of patient tests is displayed. The total number of valid patient tests and the total number of invalid patient tests are also displayed.

Print the report by pressing the **Print** button.

Press the **Back** button to return to the View Reports screen.

Press the **Main Menu** button to return to the Main Menu.

Month	Valid	Invalid	Total
Jul 2015	10	1	11
Jun 2015	11	0	11
May 2015	14	0	14
Apr 2015	17	2	19

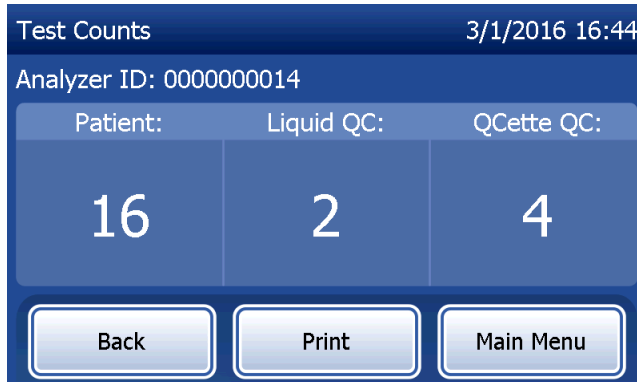
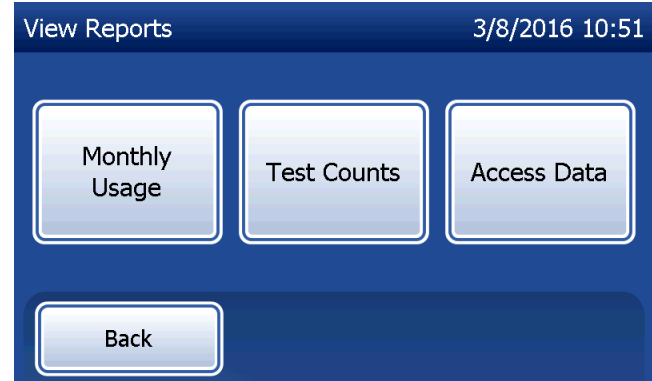
Display and Printout

MONTH	VALID	INVAL	TOTAL
MAR	0004	0000	0004
FEB	00023	00002	00025
JAN	00050	00001	00051
DEC	00017	00000	00017
NOV	00020	00000	00020
OCT	00021	00001	00022
SEP	00015	00003	00018
AUG	00006	00000	00006
JUL	00010	00001	00011
JUN	00011	00000	00011
MAY	00014	00000	00014
APR	00017	00002	00019
TTL	00208	00010	00218

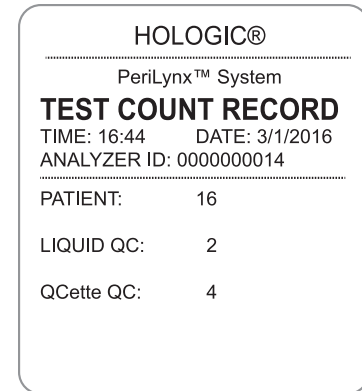
Test Counts

On the View Reports screen, touch the **Test Counts** button to view and print the number of tests by category that were performed on the analyzer.

The total numbers of patient tests, liquid control tests (Liquid QC), and QCette QC tests are displayed. Press the **Print** button to print Test Counts Report (TCR). Press the **Back** button to return to the View Reports screen. Press the **Main Menu** button to return to the Main Menu.



Display and Printout

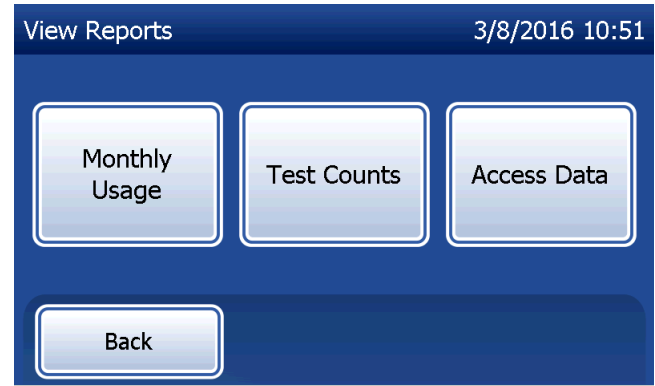


Access Data

Access Data – View/Print Data

On the View Reports screen, touch the **Access Data** button to access the patient data, QCette QC data, Liquid QC data or Calibration data stored in the analyzer.

Select the category of data records to view and/or print.



If the password protection is enabled on the analyzer, to access patient data, enter the password and press **Next**.

The screenshot shows the 'Access Data' screen with the date and time '3/1/2016 16:05'. It features a password entry field with a key icon, a 'Current password:' label, a text input field containing 'Enter or scan' and a clear button (x), and a numeric keypad showing '123'. Below the keypad is a full QWERTY keyboard layout with a 'Delete' button. At the bottom are three buttons: 'Back', 'Space', and 'Next'.

A summary of data records for the category is displayed, with the newest record at the top of the list. Patient data was chosen for this example. Use the up or down arrow to scroll through the summaries.

The screenshot shows the 'Test Patient' screen with the date and time '3/1/2016 16:45'. It displays a table of test results with three rows. The first row is highlighted. Below the table are two buttons: 'Back' and 'Main Menu'.

Date/Time	Sample ID	Result	
2/18/2016 13:32	50	61 ng/mL	▲
2/18/2016 13:21	200	135 ng/mL	
2/18/2016 11:13	10	17 ng/mL	▼

To view a data record, click on the entry. Use the up or down arrow to scroll through different data records.

Press the **Print** button to print the data record.

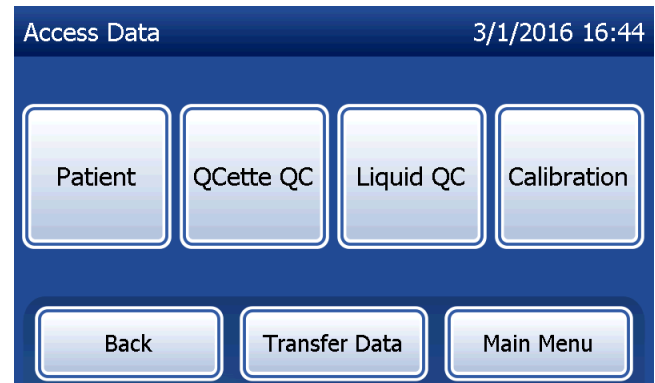
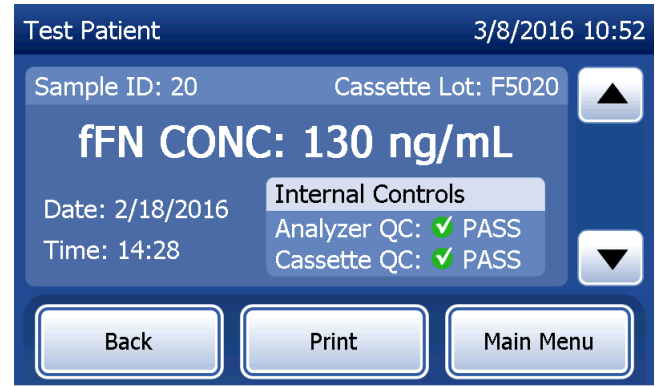
Press the **Back** button to return to the previous screen.

Press the **Main Menu** button to return to the Main Menu.

Access Data — Data Transfer

On the Access Data menu, the Transfer Data feature allows the user to transfer all of the test results stored on the analyzer to a computer connected to the analyzer through a serial cable.

Note: A maximum of 1000 patient test results, 50 QCette QC results, 50 Liquid QC results, and 50 Calibration results are stored on the analyzer.



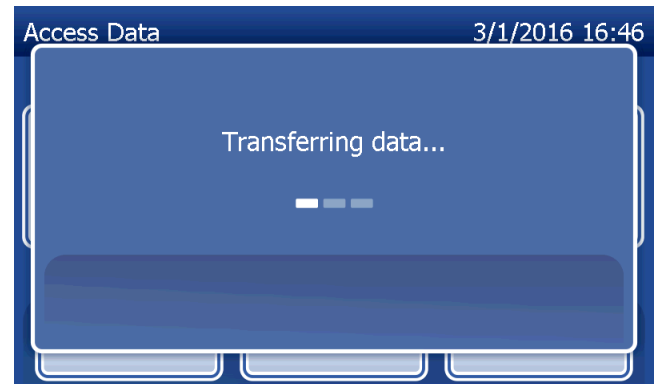
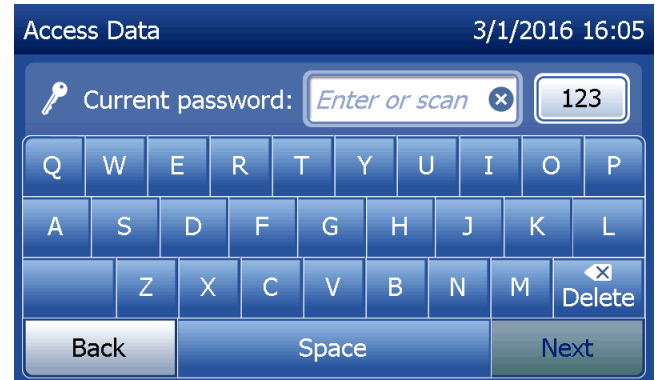
Touch **Transfer Data**.

If the password protection is enabled on the analyzer, enter the password and press **Next**.

Note: Data transferred to a computer is in ASCII format. Capture and organization of the transferred data is done at the discretion of the user. Hologic, Inc. DOES NOT provide software or technical support relating to the manipulation of data once it has left the analyzer.

This message will be displayed while the data transfer is in process.

When the transfer is complete, the View Reports screen displays.



Section 5 — Care of the Analyzer

General Cleaning

Keep the analyzer free of dust. If needed, clean the exterior, including the touch screen, with a damp cloth and mild detergent.



WARNING: Liquids **MUST NOT** be allowed to seep into the analyzer. Keep the analyzer dry at all times. Liquids leaking into the analyzer may cause damage to the electrical components or possibly electrical shock to the user.

CAUTION: DO NOT use solvents of any type on any part of the analyzer. Solvents can damage the touch screen display.

Cleaning of Cassette Insertion Site

The cassette insertion site can come into contact with biological fluids and should be cleaned regularly.

CAUTION: Use appropriate laboratory procedures for handling biohazardous materials.

Cleaning Agents Approved for Use

Reagents not listed below may cause discoloration to the analyzer case and touch screen.

The following cleaning agents may be applied with a cloth or lab wiper only. NEVER apply agents by spray.

- 70% ethanol
- General laboratory cleaning detergent with disinfectant properties

Section 6 — Printer

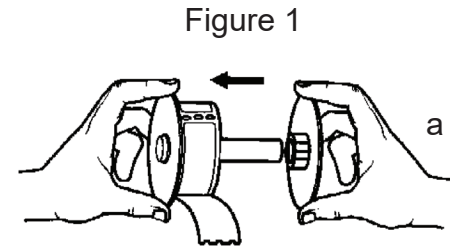
Loading Printer Labels

Refer to Section 2 — Installation, for instructions on connecting the printer to the PeriLynx analyzer.

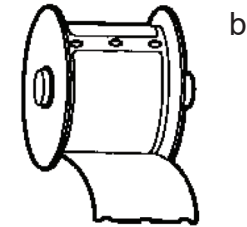
Note: DO NOT install any of the Dymo Label software that is packaged with the printer.

1. Open the printer cover for access to the interior of the printer. Remove any packing material.
2. Remove the label spool from the printer.
3. Notice that the label spool has distinct LEFT and RIGHT sides. Refer to the illustration on each piece for correct assembly. The right side slides in and out and can be removed entirely to load label rolls.
4. Remove the RIGHT SIDE of the spool by sliding it off the right end.

5. Refer to Figure 1 while following these instructions: Slide the roll of labels over the spool from right to left as shown in Figure 1(a). Then reattach the right side of the spool and push it firmly against the label roll as shown in Figure 1(b). Make sure there is no gap between the roll and the spool. The labels will feed from the bottom of the roll.

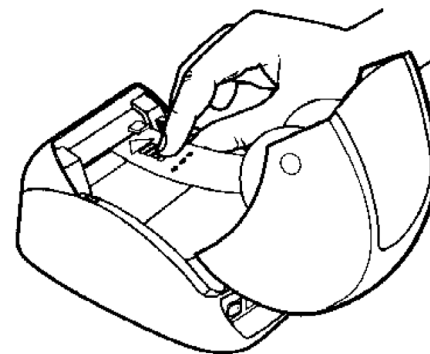


6. Ensure the power cord is connected. Turn on the printer by plugging it in to a power outlet. The power light will flash and the printer motor will run as it looks for labels to feed.
7. Holding the spool of labels in one hand, use the other hand to feed the free end of the roll into the feed slot on the inside of the printer, as shown in Figure 2. (If it is easier, rest the labels on the top edge of the printer, freeing both hands to feed the labels.)



8. Push the end into the slot until a slight resistance is felt. Continue pushing gently. The label feed motor will feed the end and carry the labels through the printer and out the exit slot. The printer will stop feeding automatically at the end of the first label. If the motor stops running while still in the process of loading labels, press the form feed button to get it started again. (To protect itself the motor stops running every few seconds.)
9. Insert the label spool into the printer. The spool will fit into the raised shoulder slots in the printer.
10. Close the cover and the printer is ready to print labels.

Figure 2



Removing an Empty Label Roll

When the printer is out of labels, the power light will flash.

1. Leave the printer turned on and open the cover. The last label on the roll may be connected to the corrugated core by a piece of tape. If it is, use scissors to cut the label between the roll and the label feed slot. Remove the label spool from the printer.
2. Press the Form Feed button on the printer's front panel to eject the remaining label stock from the printer.
3. Slide off the right side of the spool and remove the corrugated core.
4. Load a new roll of labels (see Loading Printer Labels for instructions).

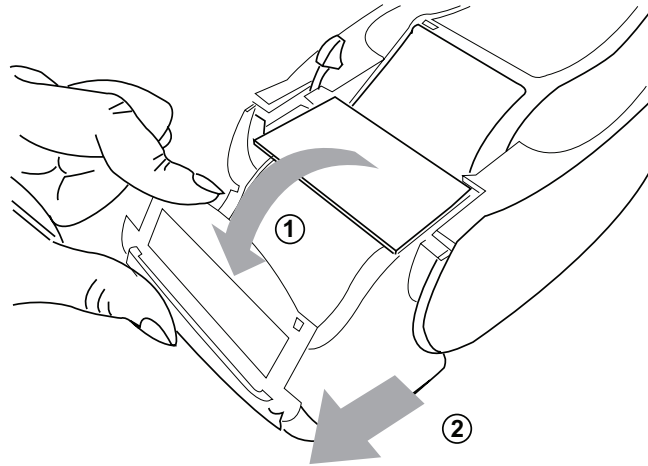
Clearing Label Jams

Note: To prevent label jams, tear off printouts as they are generated. Do not let the label roll scroll out of the printer.

If the labels jam in the printer, follow these steps to remove them.

1. Open the printer cover and use scissors to cut the label between the feed slot and the roll of labels.
2. Press the Form Feed button on the printer's front panel to advance the label through the printer. Reload the labels (see Removing an Empty Label Roll for instructions).
3. If the label will not come through the form feed slot, remove the label spool from the printer. Pull the jammed label gently back out of the printer through the feed slot.
4. If needed, the front bezel of the printer may be removed to better access the print head. Open the lid and gently pull up on the lip of the front cover (1, see below). Slide the piece forward (2). The bezel will pull off.

5. Press the level on the left of the printer forward to release the pressure of the print head against the label.
6. To reassemble the printer bezel, slide the cover back on, making sure to engage the tabs that are on the bottom as well as the top. Reload the roll of labels.



Section 7 – Troubleshooting

General Information

The PeriLynx analyzer software is designed for easy troubleshooting. Always heed the beep tones and follow the display screen prompts to obtain the best performance from your system. The following table lists potential problems, sources of trouble, and recommended solutions. Call Hologic Technical Support for any questions related to the performance of your PeriLynx system.

ITEM	PROBLEM	SOURCE	SOLUTION
1	Analyzer display screen is blank.	Analyzer power cord and/or adapter On/off switch	Ensure analyzer power cord is firmly connected to analyzer. Ensure analyzer power adapter is the adapter provided with analyzer. Ensure analyzer power adapter is plugged into a grounded AC electrical outlet. Ensure analyzer on/off switch is in the on position.

ITEM	PROBLEM	SOURCE	SOLUTION
2	Error code is displayed when analyzer is first turned on.	analyzer	<p>Turn analyzer off and back on to reinitialize the system.</p> <p>If the Error Code persists, refer to Error/Invalid Code table.</p>
3	Analysis process is interrupted and/or unusual characters appear on display screen, and the analyzer does not respond to touch screen selections.	Momentary power interruption	<p>Disconnect the printer power cord from the analyzer.</p> <p>Turn off the analyzer.</p> <p>Reconnect the printer power cord to the analyzer.</p> <p>Turn on the analyzer.</p> <p>Proceed with testing.</p>

ITEM	PROBLEM	SOURCE	SOLUTION
4	Printer fails to print	<p>Printer not connected Printer power cord</p> <p>USB cable</p> <p>Printer labels</p> <p>Printer not plugged in when test was run.</p>	<p>Ensure printer power cord is firmly connected to the analyzer. The power indicator light should be on.</p> <p>Ensure USB cable is connected to the printer and the analyzer.</p> <p>Ensure printer is not out of printer labels. To order printer labels, contact Customer Service.</p> <p>Connect the printer to the analyzer. Turn the analyzer off and back on. Recall the test result on the analyzer display screen (View Reports, Access Data, Patient. Select the report from the list to open it). Press Print on the analyzer to print the result.</p>

ITEM	PROBLEM	SOURCE	SOLUTION
5	Printer output in unusual font.	Printer	Disconnect the printer power cord from the analyzer. Turn off the analyzer. Reconnect the printer power cord to the analyzer. Turn on the analyzer.
6	Analyzer turned off after calibration, or power failure occurred after calibration.	Power	The calibration remains in memory. Reset calibration only if prompted by analyzer.
7	Cassette or QCette cannot be removed from the analyzer. (Note: do not try to force or pry it out of the analyzer.)	Analyzer	Turn analyzer off and back on to reinitialize the system. If the cassette/QCette can be easily removed, proceed with testing. If the cassette/QCette cannot be easily removed, call Technical Support.

ITEM	PROBLEM	SOURCE	SOLUTION
8	PeriLynx QCette failed to complete setup.	PeriLynx QCette or analyzer	<p>Turn analyzer off and back on to reinitialize the system.</p> <p>Ensure QCette is clean and not damaged. The QCette can be cleaned with canned air.</p> <p>Repeat QCette setup as described in Section 4 — Software Functions — Detailed Descriptions. If QCette setup is complete, run QCette QC, followed by Run Liquid QC.</p> <p>Do not bump or jar analyzer or QCette during the test.</p> <p>If the QCette setup fails a second time, call Technical Support.</p>

ITEM	PROBLEM	SOURCE	SOLUTION
9	PeriLynx QCette failed during daily instrument verification.	PeriLynx QCette or analyzer	<p>Turn analyzer off and back on to reinitialize the system.</p> <p>Confirm that the QCette serial number on the device matches the serial number programmed in the analyzer, indicated on the QCette QC Result printout.</p> <p>Ensure QCette is clean and not damaged. The QCette may be cleaned with canned air.</p> <p>Run QCette QC. If this passes, no further troubleshooting is required.</p> <p>If Run QCette QC fails, perform QCette Setup. (From the Main menu, select Adjust Settings, then QCette Setup.) When QCette Setup is complete, Run QCette QC, followed by Run Liquid QC. If both pass, no further troubleshooting is required.</p> <p>If Run QCette QC fails a second time, call Technical Support.</p>

ITEM	PROBLEM	SOURCE	SOLUTION
10	Liquid control result is outside the range of acceptable results.	Liquid control	<p>Verify that the Rapid fFN 10Q Cassettes have not expired and have been stored properly. Ensure the cal code programmed in the instrument matches the cal code on the cassette box.</p> <p>Verify the control has not expired, and is neither cloudy nor discolored.</p> <p>If contamination of the controls is suspected, open a new box of controls.</p> <p>Review the Rapid fFN Control Kit directional insert to ensure the correct procedure was followed. Repeat the test on a new cassette. If control result is acceptable, no further troubleshooting is required.</p> <p>If the control result is outside the range of acceptable results a second time, call Technical Support.</p>

ITEM	PROBLEM	SOURCE	SOLUTION
11	Invalid liquid control test result.	Internal Controls Analyzer QC: Fail Cassette QC: Pass	<p>Refer to Error/Invalid Code table.</p> <p>Turn analyzer off and back on to reinitialize the system.</p> <p>Run QCette QC. If the Run QCette QC result is Pass, retest the control on a new cassette. If both pass, no further troubleshooting is required.</p> <p>If the result of the Run QCette QC result is Fail, call Technical Support.</p>
		Internal Controls Analyzer QC: Pass Cassette QC: Fail	<p>Verify that 200 μL of control was dispensed.</p> <p>Review the Rapid fFN Control Kit directional insert to ensure the correct procedure was followed. Repeat the test on a new cassette. If control result is acceptable, no further troubleshooting is required.</p> <p>Do not bump or jar the analyzer or the cassette during the test.</p> <p>If control is invalid a second time, call Technical Support.</p>

ITEM	PROBLEM	SOURCE	SOLUTION
12	Invalid patient test result	Internal Controls Analyzer QC: Fail Cassette QC: Pass	<p>Refer to Error/Invalid Code table.</p> <p>Turn analyzer off and back on to reinitialize the system.</p> <p>Rerun the Run QCette QC. If the result is Pass, retest the sample on a new cassette. If both pass, no further troubleshooting is required.</p> <p>If the Patient Test result is Invalid, call Technical Support.</p>
		Internal Controls Analyzer QC: Pass Cassette QC: Fail	<p>Verify that 200 µL of sample was dispensed.</p> <p>Review the Rapid fFN 10Q Cassette Kit directional insert to ensure the correct procedure was followed. Repeat the test on a new cassette.</p> <p>Examine the cassette. Viscous patient samples can cause sample flow across the membrane to be incomplete. Look to see if there is evidence of sample contamination (lubricants, soap, disinfectant, creams).</p> <p>Retest the sample on a new cassette. If the problem is not corrected, contact the physician and recommend recollection in 24 hours.</p>

Error/Invalid Codes

ERROR CODE	DEFINITION	TROUBLESHOOTING PROCEDURE
003, 004, 007, 020, 024, 100, 103, 104, 107, 120, 124	Internal Controls Cassette QC Failure	Refer to Troubleshooting Items 11 and 12.
142A	Dark Count Out of Range	Turn analyzer off and back on to reinitialize the system. Rerun Run QCette QC. If Run QCette QC passes, continue with normal operation. If Run QCette QC fails, contact Technical Support.
142B	Temperature Error	Turn analyzer off and back on to reinitialize the system. Rerun Run QCette QC. If Run QCette QC passes, continue with normal operation. If Run QCette QC fails, contact Technical Support.
0622	Possible Voltage Problem	Turn analyzer off and back on to reinitialize the system. Rerun Run QCette QC. If Run QCette QC passes, continue with normal operation. If Run QCette QC fails, contact Technical Support.
0720 0721	Possible Motor Problem	Turn analyzer off and back on to reinitialize the system. Rerun Run QCette QC. If Run QCette QC passes, continue with normal operation. If Run QCette QC fails, contact Technical Support.

If analyzer errors persist or recur, call Technical Support.

ERROR CODE	DEFINITION	TROUBLESHOOTING PROCEDURE
OD24	Possible QCette Problem	Turn analyzer off and back on to reinitialize the system. Clean the QCette according to its directional insert. Repeat QCette setup (refer to Troubleshooting Item 8).
OE21	High Light Level	Turn analyzer off and back on to reinitialize the system. Identify if there is any new source of bright light (recent relocation near a window, lab lights replaced, window blinds open). Remove the source of excess light if possible or relocate the analyzer. Refer to Troubleshooting Items 11 and 12. Rerun Run QCette QC. If Run QCette QC passes, continue with normal operation. If Run QCette QC fails, contact Technical Support.
OE22, OE23	Possible Optics Problem	Turn the analyzer off and back on to reinitialize the system. Rerun Run QCette QC. If Run QCette QC passes, continue with normal operation. If Run QCette QC fails, contact Technical Support.
Other Codes		Call Technical Support.

If analyzer errors persist or recur, call Technical Support.

Section 8 — Service

Technical Support

Analyzer

The PeriLynx analyzer is a self-contained instrument. There are no user-serviceable parts. With proper care and use, the analyzer should operate reliably with minimal attention. If a problem should occur, refer to Section 7, Troubleshooting. For analyzer service, contact Hologic Technical Support.

Printer

The printer is a self-contained instrument. If a problem should occur, refer to Section 7 — Troubleshooting. For printer service, contact Hologic Technical Support.

Barcode scanner (optional)

The barcode scanner is a self-contained instrument. If a problem should occur, contact Hologic Technical Support.

Contact Information

Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121 USA
www.hologic.com

Technical Support (Outside the USA and Canada)

Tel:

Asia	+852 3526 0718	Netherlands:	0800 0226782
Australia:	+61 2 9888 8000	Norway:	800 15564
Austria:	0800 291919	Portugal:	800 841034
Belgium:	0800 77378	Spain:	900 994197
Denmark:	8088 1378	South Africa:	0800 980 731
Finland:	0800 114829	Sweden:	020 797943
France:	0800 913659	Switzerland:	0800 298921
Germany:	0800 1830227	UK:	0800 0323318
Ireland (Rep):	1 800 554144	Other countries:	00800.800.29892
Italy:	800 786308		

Intl Fax number: 0041.21.633.39.10

E-mail: InternationalTechSupport@Hologic.com

Replacement Parts

Item	Catalog Number
Printer Labels	52660-001
PeriLynx QCette	PRD-04007
Rapid fFN 10Q Liquid Controls Kit	PRD-01019
Specimen Collection Kit	PRD-01020
Rapid fFN Cassettes, 26-pack box	PRD-01018
Barcode scanner	MEL-00970
PeriLynx System User Manual	MAN-08809-001

Contact fFN Customer Service to order replacement parts.

Contact Information

Customer Service (Outside the USA and Canada)

Please contact your nearest location. To find the nearest location, please visit

www.ffntest.com

or www.hologic.com

or telephone 00800-800-29892

A copy of Hologic's limited warranty and other terms and conditions of sale may be obtained by contacting Customer Service at the numbers listed above.

PeriLynx™ System

Analyzer Serial Number _____

Printer Serial Number _____

Barcode Scanner Serial Number (optional) _____

Shipment Date _____