

RapidfEN[®]

10Q System



User Manual

IMPORTANT: Read the entire manual before operating the Rapid fFN® 10Q System.

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The Rapid fFN® 10Q Analyzer is covered by U.S. patent number 6,267,722. The Rapid fFN® 10Q QCette is covered by U.S. patent number Des. 432,244.

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TABLE OF CONTENTS

Section		Page
I	Introduction	
	• Intended Use	1-1
	• General Description	1-1
	• Components of the Analyzer	1-2
	• Keypad	1-3
	• Cassette Insertion Site	1-4
	• Displayed/Printed Results	1-5
	• Specifications	1-6
	• Cautions and Warnings	1-8
2	Installation	
	• General	2-1
	• Environmental Factors	2-1
	• Unpacking	2-2
	• System Setup	2-4
	• Getting Started	2-6
	• Setting the Date and Time	2-7
	• Factory Default Settings	2-8

TABLE OF CONTENTS

Section	Page
• Shutdown	2-8
• Extended Shutdown	2-8
3 General Operating/Testing Instructions	
• Starting the System	3-1
• Overview of Rapid fFN 10Q Analyzer Menu	3-2
• Typical Menu Item Sequences	3-3
• Key to User Entry Fields	3-4
• Keypad Functions	3-5
• Keypad Entries	3-6
• Daily QC - Quick Reference	3-11
• Test Patient - Quick Reference	3-12
• Set Calibration - Quick Reference	3-14
• Liquid Controls - Quick Reference	3-15
4 Software Functions – Detailed Descriptions	
• Startup Screen	4-1
• Main Menu	4-2
• Set Calibration	4-3

TABLE OF CONTENTS

Section	Page
• Test Patient	4-6
• Daily QC	4-12
• Liquid Controls	4-16
• Access Data	4-21
• View/Print Data	4-21
• Data Transfer	4-23
• View Setup	4-24
• Change Setup	4-25
• Date/Time	4-25
• Autoprint	4-28
• Rapid fFN QCette Setup	4-29
• Software Update	4-33
• Test Counts	4-34
• Usage Report	4-35
5 Care of the Analyzer	
• General Cleaning	5-1
• Cleaning of Cassette Insertion Site	5-1
• Cleaning Agents Approved for Use	5-1

TABLE OF CONTENTS

Section		Page
6	Printer	
	• Loading Printer Labels	6-1
	• Removing an Empty Label Roll	6-4
	• Clearing Label Jams	6-5
7	Troubleshooting	
	• General Information	7-1
	• Troubleshooting Table	7-1
	• Error/Invalid Codes	7-10
8	Service and Warranty	
	• Technical Support	8-1
	• Contact Information — Technical Support	8-1
	• Replacement Parts	8-3
	• Contact Information — fFN Customer Service	8-4
	• Warranty	8-5

SECTION I — INTRODUCTION



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

INTENDED USE

The Hologic Rapid fFN[®] 10Q 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 Rapid fFN 10Q QCette for the detection of fetal fibronectin (fFN) in cervicovaginal secretions. Refer to the directional insert for the Rapid fFN 10Q Cassette for detailed intended use information.

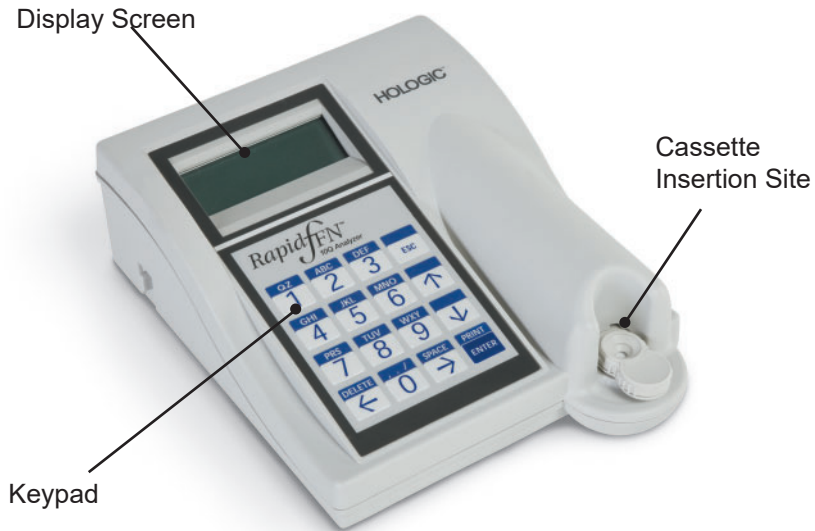
GENERAL DESCRIPTION

The Rapid fFN 10Q Analyzer is an electronic optical reflectance device that converts a colorimetric reaction from a cassette into a digitized format. 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 display screen, the keypad, and the cassette insertion site.





KEYPAD

Numeric — Use keypad to enter numerical characters from **0 to 9**.

Alpha — Use keypad to enter alpha characters from **A to Z**.

Functions — Up, down, left, right arrows act as function keys to move through the menus and select options.

DELETE, ESC (escape), SPACE, PRINT/ENTER function keys provide further functionality for using the menu options.

See Chapter 3, General Operating, for a full description of using the keypad.

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 Rapid fFN 10Q Cassette. This area of the instrument should be cleaned regularly (see Section 5, Care of the Analyzer).

Note: Insert a Rapid fFN **10Q** Cassette or Rapid fFN **10Q** QCette *only*.



DISPLAYED/PRINTED RESULTS

Each menu function result is displayed on the analyzer display screen. A result may require one or more screens to display all of the data associated with the result. With AUTOPRINT 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

Rapid fFN 10Q
03:00 PM 10/26/13
PT:JANE DOE 123
fFN:160 ng/mL →

USER:JOHN SMITH
ANALYZER QC: PASS
CASSETTE QC: PASS
← →

CAL CODE:95HYA-76YTT
CASSETTE LN:L1002
ANALYZER ID:G0237
ESC-MAIN MENU ←

Displayed

HOLOGIC Rapid fFN®

Rapid fFN 10Q RESULT
fFN CONC: 160 ng/mL
TIME: 03:00 PM DATE: 10/26/13

PATIENT: JANE DOE 123
USER: JOHN SMITH
CASSETTE LOT: L1002
CALIBRATION CODE: 95HYA-76YTT
ANALYZER ID: G0237

INTERNAL CONTROLS
ANALYZER QC: PASS
CASSETTE QC: PASS

Printed

SPECIFICATIONS

Power Supply	UL 15 VDC listed power supply
Memory Capacity	50 Calibration Records 50 QCette Records 50 Control Records 1000 Patient Records
Display	4 lines 20 characters per line Alphanumeric 5 x 8 matrix Supertwist LCD Black characters with gray background
Keypad	3.5 x 4.5 inches Tactile membrane Alphanumeric keys

Dimensions	Length — 8.9 inches Width — 6.9 inches Height — 1.0 to 3.0 inches Weight — 1.56 pounds
Operating Temperature	15° to 30°C 59° to 86°F
Operating Humidity	20% to 80%, non-condensing
A.C. Supply	100-240VAC 50-60 Hz 0.7A
Input Connector	Coaxial power plug with positive center conductor
Output Connectors	9 pin data connector 2 host USB connectors

CAUTIONS AND WARNINGS

There are no known hazards associated with the Rapid fFN 10Q 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.



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 keypad with undiluted bleach solution or other solvents. Caustic cleaning solutions can damage the keypad.

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;
In Vitro Diagnostic (IVD) Medical Equipment.

EN61010-2-101 Electrical Equipment for Measurement, Control and Laboratory Use; Part 101; Particular Requirements for *In Vitro Diagnostic* (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)

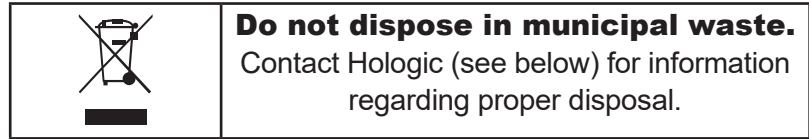
Hologic is dedicated to meeting country specific requirements associated with the environmentally sound treatment of our products. Our objective is to reduce the waste arising from our electrical and electronic equipment. Hologic realizes the benefits of subjecting such WEEE equipment to potential reuse, 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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Authorized Representative - Outside of U.S.	Hologic BVBA Da Vincilaan 5 1930 Zaventem Belgium

Symbols Used on the Instrument

The following symbols are used on this instrument:



Warning, refer to accompanying documents.



Waste Electrical and Electronic Equipment - contact Hologic for disposal of the instrument.



Lot



Catalog Number



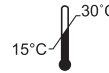
Serial Number



Manufactured by



Authorized Representative in the European Community



Store between 15°C and 30°C



For *in vitro* diagnostic testing

SECTION 2 — INSTALLATION

GENERAL

This section provides detailed installation instructions for the Rapid fFN 10Q System. Follow installation steps carefully to insure proper installation and operation.

ENVIRONMENTAL FACTORS

The Rapid fFN 10Q 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 Rapid fFN 10Q 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 (64° 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).

UNPACKING

Rapid fFN 10Q 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:

- Rapid fFN 10Q Analyzer
- Wall Mount Power Adapter (with one or more AC plugs for international compatibility)
- User Manual
- Rapid fFN 10Q 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 (one or more for international compatibility)
- Desktop Power Adapter
- USB Cable



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

SYSTEM SETUP

1. The Analyzer and Printer should be placed on a flat, level surface. Verify that the power switch on the left side of the analyzer is set to the OFF position.

Note: Apply power to the printer before applying power to the analyzer.

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

2. Plug the desktop power adapter output jack into the receptacle labeled 24V DC on the bottom of the printer. Plug one end of the appropriate power cord into the desktop power adapter. Plug the other end of the power cord into an AC power outlet. The light on the front panel of the printer shows that power is on.
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 either of the USB ports labeled 'Printer' on the analyzer.



System



Printer



Analyzer

4. If necessary, configure the wall mount adapter with the correct AC plug corresponding to room power outlets.
5. Plug the output jack from the wall mount power adapter into the rear of the analyzer at the receptacle marked 15 VDC. Plug the wall mount adapter into an AC power outlet.

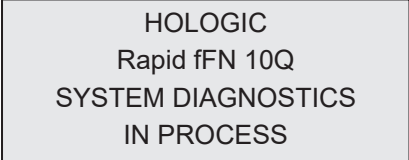
Caution: Only power adapters provided with the Rapid fFN 10Q Analyzer and printer may be used. Any substitutions can result in damage to the Rapid fFN 10Q Analyzer and printer.

GETTING STARTED

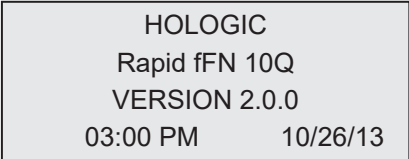
Turn the analyzer power switch to the ON position. The power switch is located on the left side of the instrument. (If the analyzer does not turn on, see Section 7, Troubleshooting, Item 1.)

Upon power up, the analyzer displays the message **INITIALIZING** for 17 seconds. Then it beeps and the analyzer will perform **SYSTEM DIAGNOSTICS** (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.



HOLOGIC
Rapid fFN 10Q
SYSTEM DIAGNOSTICS
IN PROCESS



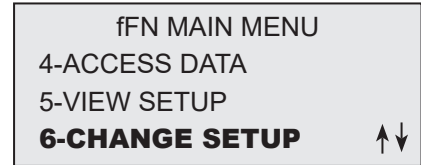
HOLOGIC
Rapid fFN 10Q
VERSION 2.0.0
03:00 PM 10/26/13

Once SYSTEM DIAGNOSTICS is complete, the display will change to the software **VERSION, DATE,** and **TIME** for five seconds, and then to the fFN Main Menu. The date and time may need to be reset for your time zone.

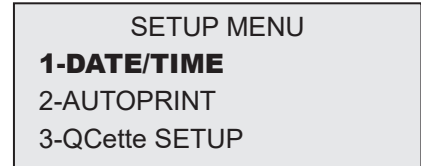
SETTING THE DATE AND TIME

Refer to Section 3, General Operating, for a description of using the keypad.

1. From the Main Menu, select CHANGE SETUP by pressing the ↓ to get to the second page of the Main Menu. Press 6 for CHANGE SETUP. This will display the SETUP MENU.



2. From the SETUP MENU, press 1 to display DATE/TIME and follow the prompts.



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

FACTORY DEFAULT SETTINGS

The Rapid fFN 10Q 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:

AUTOPRINT

Factory setting is Autoprint 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.

SHUTDOWN

The system may be left plugged in and idle when not in use. If the system is to be shutdown make sure it is idle. Move the power switch on the left side of the analyzer to the OFF position. The printer is always powered on. To remove power from the printer, unplug the power cord from the electrical outlet.

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 Rapid fFN 10Q 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 left side 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** for 17 seconds. Then it beeps and the analyzer will perform **SYSTEM DIAGNOSTICS** (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 plugged in, the printer is continuously powered on. Ensure labels are in the printer. See Section 6, Printer, for loading printer labels.

HOLOGIC
Rapid fFN 10Q
SYSTEM DIAGNOSTICS
IN PROCESS

HOLOGIC
Rapid fFN 10Q
VERSION 2.0.0
03:00 PM 10/26/13

OVERVIEW OF Rapid fFN 10Q ANALYZER MAIN MENU

fFN MAIN MENU	Purpose
1-TEST PATIENT	Runs the Rapid fFN 10Q test on a patient sample.
2-SET CALIBRATION	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.
3-DAILY QC	Compares functional parameters of the QCette against those of its original setup. Ensures the analyzer is functioning properly. Performed daily.
4-ACCESS DATA	View/print the results of patient tests, QCette and Control checks and System Calibration results. Allows for transfer of data via the data port.
5-VIEW SETUP	View current setup of cal code, date/time and autoprint setting without inadvertently changing them.
6-CHANGE SETUP	Allows change to date/time, autoprint setting or to perform QCette setup. Allows Hologic Technical Support to update the software version.
7-TEST COUNTS	View/print the number of tests performed on the analyzer to date: Patient, Control, QCette.
8-LIQUID CONTROLS	Runs the liquid control samples on the analyzer to ensure the Rapid fFN 10Q System functions properly. Performed at installation and with every cassette lot change or shipment.
9-USAGE REPORT	View/print the total number of patient test results over the past 12 months.

TYPICAL MENU ITEM SEQUENCES

Upon System Installation	Routine Daily Use	New Lot of Cassettes
6 Set Date /Time	3 Daily QC	2 Set Calibration
6 Select Autoprint On/Off	1 Test Patient	3 Daily QC
6 QCette Setup	View/Print Results	8 Liquid Controls
2 Set Calibration		1 Test Patient
3 Daily QC		View/Print Results
8 Liquid Controls		
1 Test Patient		
View/Print Results		

KEY TO USER ENTRY FIELDS

Field	Length	Required Format
User ID	Up to 15 characters	Any combination of letters and numbers. An entry must be made.
Patient 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.
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. An entry must be made.

KEYPAD FUNCTIONS

(Vertical Scroll)

Alpha characters — Use ↑ ↓ to navigate through the alphanumeric keys when selecting an alpha character.

Scrolling through Data Records — Use ↑ ↓ when scrolling through data records in ACCESS DATA mode.

Menu Screens — Some menus require up to three screens to display all of the options. Use ↑ ↓ to go to the next or previous screen of the menu.

(Left Arrow Key)

Previous Page — Use ← to go to the previous page within a data record.

Delete — Use **DELETE** to delete characters to the left of the cursor.

(Right Arrow Key)

Next Page — Use → to go to the next page within a data record.

Space — Use **SPACE** to enter a space in the position of the cursor.



(Print/Enter Key)

Accept/Confirm — Press **ENTER** to accept or confirm an entry in any data entry field.

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

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



(Escape Key)

Press ESC to return to the most recent Menu screen, unless otherwise specified. If ESC is pressed in any screen requiring data entry, all entries will revert to the previous setting.



KEYPAD ENTRIES

Entries of **numerical characters** require pressing the appropriate numeric key.

Entries of **alpha characters** require pressing the numeric key containing the alpha character and the ↑ or ↓ arrows (scroll keys).



Example – to enter Liquid Control Lot Number **C9123**.

1 – Press **2**. Use ↑ arrow until **C** appears on the display screen.

Note: The ↑ arrow will scroll repetitively through the characters **2-A-B-C**. The ↓ arrow will scroll repetitively through the characters **2-C-B-A**.

LEVEL 1 CONTROL LOT #
>2
ENTER - CONFIRM

LEVEL 1 CONTROL LOT #
>C
ENTER - CONFIRM

2 – Press **9**.

LEVEL 1 CONTROL LOT #
>C9
ENTER - CONFIRM

3 – Press each subsequent number **1, 2, 3**.

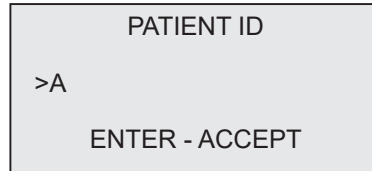
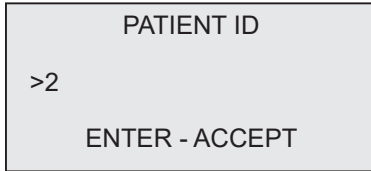
LEVEL 1 CONTROL LOT # >C912_ ENTER - CONFIRM
--

4 – Press **ENTER** after all entries have been made.

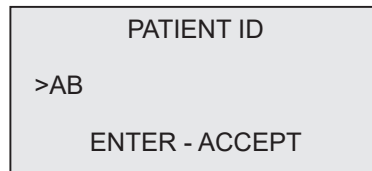
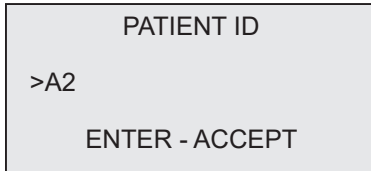
LEVEL 1 CONTROL LOT # >C9123 ENTER - CONFIRM
--

Example — to enter Patient Name **ABE**

1 – Press **2**. Use ↑ or ↓ arrow until **A** appears on the display screen.



2 – Press **2** again. Use ↑ or ↓ arrow until **B** appears on the display screen.



3 – Press **3** to enter the next letter. Use ↑ or ↓ arrow until **E** appears on the display screen.

PATIENT ID
>AB3
ENTER - ACCEPT

PATIENT ID
>ABE
ENTER - ACCEPT

4 – Press **ENTER** after all entries have been made.

DAILY QC - Quick Reference

Daily QC should be performed at least once every 24 hours. Note that Main Menu item 3-DAILY QC will blink if 24 hours have passed since the last performance of this check.

From the Main Menu select 3-DAILY QC.

Enter User ID and press ENTER.

Enter the QCette serial number, or verify, if it is already entered.

Insert QCette and press ENTER.

Results will be displayed and printed in 3 minutes.

If the QCette does not pass, see Section 7, Troubleshooting, Item 10.

```
DAILY QC
USER ID
>JOHN SMITH
ENTER-CONFIRM
```

```
DAILY QC
ENTER QCette SN
>004640
ENTER-CONFIRM
```

```
INSERT QCette
ENTER-CONTINUE
```

```
TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE
```

```
QCette
03:00 PM 10/26/13
SYSTEM: PASS
USER:JOHN SMITH →
```

TEST PATIENT - Quick Reference

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

From the Main Menu select 1-TEST PATIENT.

Enter User ID and press ENTER.

Enter the last two digits of the cassette lot# (on cassette pouch) and press ENTER.

Enter the patient accession number and press ENTER.

Remove the patient cassette from its pouch.
Insert the cassette into the analyzer and press ENTER.

fFN MAIN MENU 1-TEST PATIENT 2-SET CALIBRATION 3-DAILY QC ↓
--

TEST PATIENT USER ID >JOHN SMITH ENTER-CONFIRM

TEST PATIENT CASSETTE LOT# >L1002 ENTER-ACCEPT

PATIENT ID >JANE DOE 123 ENTER-ACCEPT

INSERT CASSETTE PRESS ENTER TO CONTINUE

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

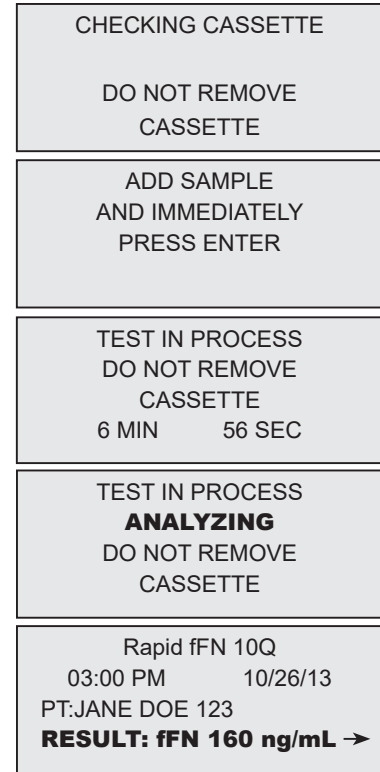
The instrument will beep repeatedly and the display will read ADD SAMPLE AND IMMEDIATELY PRESS ENTER.

Add 200 uL of patient sample and press ENTER.

The analyzer will begin a 7-minute incubation countdown.

Following incubation, the analyzer will begin analysis of the cassette.

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



SET CALIBRATION - Quick Reference

Calibration must be set when changing cassette lots.

From the Main Menu, select 2 - SET CALIBRATION.

Enter User ID and press ENTER.

Enter the cassette lot# (on cassette pouch) and press ENTER.

Enter the CALIBRATION CODE# (on the cassette box) and press ENTER.

Calibration results will be displayed and printed.

```
fFN MAIN MENU
1-TEST PATIENT
2-SET CALIBRATION
3-DAILY QC
```



```
SET CALIBRATION
  USER ID
>JOHN SMITH
  ENTER-CONFIRM
```

```
SET CALIBRATION
  CASSETTE LOT#
>L1002
  ENTER-ACCEPT
```

```
SET CALIBRATION
  CALIBRATION CODE#
>95HYA-76YTT
  ENTER-ACCEPT
```

```
Rapid fFN 10Q
03:00 PM      10/26/13
SYSTEM CALIBRATED
USER:JOHN SMITH →
```

LIQUID CONTROLS - Quick Reference

Run Liquid Controls with every cassette lot change.

From the Main Menu, select 8 - LIQUID CONTROLS.

Enter User ID and press ENTER.

Enter the cassette lot# (on cassette pouch) and press ENTER.

Select Level 1 or Level 2.

Enter the control lot# (on bottle label) and press ENTER.

```
      fFN MAIN MENU
      7-TEST COUNTS
      8-LIQUID CONTROLS
      9-USAGE REPORT      ↓
```

```
      RUN CONTROL
      USER ID
      >JOHN SMITH
      ENTER-CONFIRM
```

```
      RUN CONTROL
      CASSETTE LOT #
      >L1002
      ENTER-ACCEPT
```

```
      CONTROL TEST MENU
      1-LEVEL 1
      2-LEVEL 2
```

```
      LEVEL 1 CONTROL LOT#
      >C9123

      ENTER-CONFIRM
```

Insert cassette and press ENTER.

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

The instrument will beep repeatedly and the display will read ADD SAMPLE AND IMMEDIATELY PRESS ENTER.

Add 200 uL of control sample and press ENTER.

The analyzer will begin a 7-minute incubation countdown.

Following incubation, the analyzer will begin analysis of the cassette.

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

Note: Both a Level 1 and a Level 2 control sample must be run. Repeat the test with the other control sample and a fresh cassette.

If the Liquid Control result does not pass, refer to Section 7, Troubleshooting, Item 11.

INSERT CASSETTE
PRESS ENTER
TO CONTINUE

CHECKING CASSETTE

DO NOT REMOVE
CASSETTE

ADD SAMPLE
AND IMMEDIATELY
PRESS ENTER

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

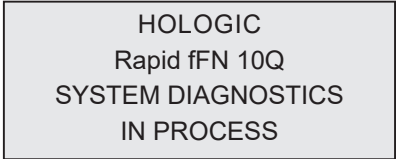
Rapid fFN 10Q
03:00 PM 10/26/13
LEVEL 1: M1023
fFN: 31 ng/mL →

SECTION 4 — SOFTWARE FUNCTIONS — DETAILED DESCRIPTIONS

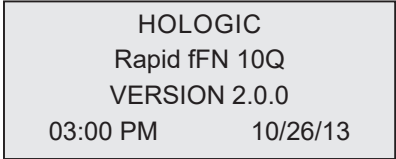
STARTUP SCREEN

Upon power up, the analyzer displays the message **INITIALIZING** for 17 seconds. Then it beeps and the analyzer will perform **SYSTEM DIAGNOSTICS** (a self-test of the analyzer components).

Following the self-test, the analyzer displays the software version and the current date and time for five seconds before displaying the Main Menu.



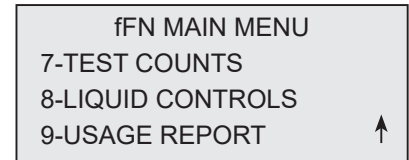
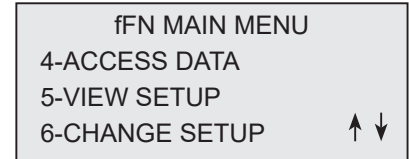
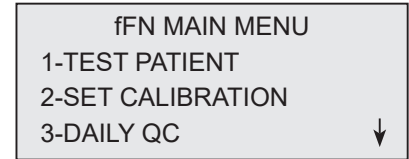
HOLOGIC
Rapid fFN 10Q
SYSTEM DIAGNOSTICS
IN PROCESS



HOLOGIC
Rapid fFN 10Q
VERSION 2.0.0
03:00 PM 10/26/13

MAIN MENU

The Main Menu, displayed over three screens, consists of Test Patient, Set Calibration, Daily QC, Access Data, View Setup, Change Setup, Test Counts, Liquid Controls, and Usage Report. Selecting the number in front of each option initiates that procedure or displays a submenu.

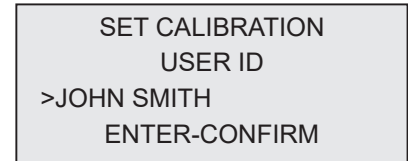
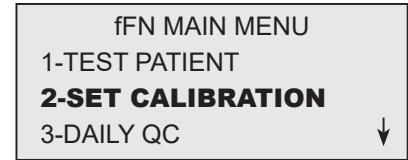


SET CALIBRATION

Option 2 on the Main Menu screen allows the user 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, menu option 2 will flash. 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 ENTER to accept the ID. This field will accept 15 alpha or numeric characters.



The CASSETTE LOT# 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., L1002).

The CALIBRATION 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.

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

```
SET CALIBRATION  
CASSETTE LOT#  
>L1002  
ENTER-ACCEPT
```

```
SET NEW CALCODE  
CALIBRATION CODE#  
>95HYA-76YTT  
ENTER-ACCEPT
```


Calibration Data Record — This record is displayed over two screens. Each screen can be accessed by using the → and ← keys. The complete record will be printed automatically if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

```
Rapid fFN 10Q
03:00 PM      10/26/13
SYSTEM CALIBRATED
USER:JOHN SMITH      →
```

```
CAL CODE:95HYA-76YTT
CASSETTE LN:L1002
ANALYZER ID G0237
ESC-MAIN MENU      ←
```

Display and Printout

```
-----
HOLOGIC Rapid fFN®
-----
Rapid fFN 10Q Analyzer
SYSTEM CALIBRATED
TIME: 03:00 PM      DATE: 10/26/13
-----
USER: JOHN SMITH
CASSETTE LOT: L1002
CALIBRATION CODE: 95HYA-76YTT
ANALYZER ID: G0237
```

TEST PATIENT

Option 1 on the Main Menu screen allows the user to test a patient sample. Follow the analyzer prompts.

The USER ID must be entered to proceed to the next step. Press ENTER to accept the ID. This field will accept 15 alpha or numeric characters.

The CASSETTE LOT# must be entered to proceed to the next step. For convenience, the last 2 numbers only can be entered if the lot has not changed. The CASSETTE LOT# is located on the cassette pouch. The software requires that the lot number is entered in the correct format: one alpha character followed by four numeric characters (e.g., L1002).

Note: If the CASSETTE LOT# has changed, SET CALIBRATION must be performed.

```
fFN MAIN MENU
1-TEST PATIENT
2-SET CALIBRATION
3-DAILY QC
```

```
TEST PATIENT
  USER ID
>JOHN SMITH
  ENTER-CONFIRM
```

```
TEST PATIENT
  CASSETTE LOT#
>L1002
  ENTER-ACCEPT
```

The analyzer automatically compares the CASSETTE LOT# used to set calibration with the cassette lot number used for patient testing. If the LOT NUMBERS do not match, the test process cannot continue. When this occurs, the cassette lot number used for calibration will be displayed, and the user is prompted to recalibrate the system.

```
CASSETTE LOT CHANGED
CALIBRATE SYSTEM
  L1002
ESC-MAIN MENU
```

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

```
PATIENT ID
>JANE DOE 123

ENTER-ACCEPT
```

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

```
REMOVE CASSETTE

PRESS ENTER
TO CONTINUE
```

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

INSERT CASSETTE
PRESS ENTER
TO CONTINUE

This message will be displayed if a cassette is not inserted. Press ENTER to return to the previous screen.

CASSETTE NOT
INSERTED

ENTER-CONTINUE

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

CHECKING CASSETTE

DO NOT REMOVE
CASSETTE

A 30-second timer starts during which time this message flashes and the analyzer beeps. Add 200 uL of patient sample and **immediately** press ENTER.

ADD SAMPLE
AND IMMEDIATELY
PRESS ENTER

If the patient sample is not added and ENTER not pressed within allotted time, the test process cannot continue. This message will be displayed. Press ESC to return to the Main Menu. No record of the test will be held in memory.

SAMPLE NOT ADDED
WITHIN ALLOTTED TIME

ESC-MAIN MENU

Once the sample is added, the analyzer will begin a 7-minute incubation countdown. To abort the test, press ESC. Pressing ESC will terminate the test and the data will be lost.

TEST IN PROCESS
DO NOT REMOVE
CASSETTE

6 MIN 56 SEC

Upon completion of the 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.

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

TEST WARNING: This message will be displayed if ESC was pressed during testing. Select ENTER to continue test, or ESC to end test. This message will hold for 5 seconds and then revert back to its respective screen. If the test is cancelled, a new cassette will be required to repeat the test.

CANCEL TEST?
 ENTER-CONTINUE
 ESC-MAIN MENU
 6 MIN 37 SEC

Patient Data Record — This record is displayed over three screens. Each screen can be accessed by using the ← and → keys. The complete record will be printed automatically if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

Rapid fFN 10Q
 03:00 PM 10/26/13
 PT:JANE DOE 123
fFN:160 ng/mL →

USER:JOHN SMITH
 ANALYZER QC: PASS
 CASSETTE QC: PASS ← →

CAL CODE:95HYA-76YTT
 CASSETTE LN:L1002
 ANALYZER ID:G0237
 ESC-MAIN MENU ←

Display and Printout

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

HOLOGIC Rapid fFN®

 Rapid fFN 10Q RESULT
fFN CONC: 160 ng/mL
 TIME: 03:00 PM DATE: 10/26/13

 PATIENT: JANE DOE 123
 USER: JOHN SMITH
 CASSETTE LOT: L1002
 CALIBRATION CODE: 95HYA-76YTT
 ANALYZER ID: G0237

 INTERNAL CONTROLS
 ANALYZER QC: PASS
 CASSETTE QC: PASS

An INVALID result should be repeated. (See Section 7, Troubleshooting, Item 13.)

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 Rapid fFN 10Q Analyzer hardware.

DAILY QC

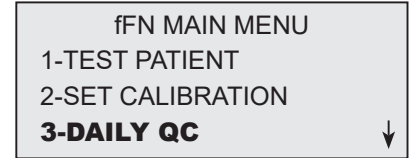
Prior to running the Rapid fFN 10Q QCette® for the first time, QCette SETUP must be performed. See page 4-29. Refer to the Rapid fFN 10Q QCette directional insert for more information.

Daily QC should be performed at least once every 24 hours. Note that Main Menu item 3-DAILY QC will blink if 24 hours have passed since the last performance of this check.

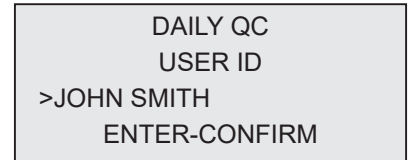
Option 3 on the Main Menu screen allows the user to run the QCette.

The USER ID must be entered to proceed to the next step. Press ENTER to accept the ID. This field will accept 15 alpha or numeric characters.

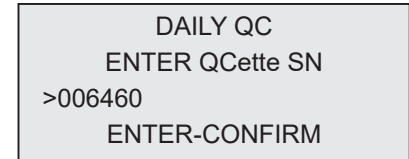
The QCette SN (serial number) is displayed. (It was originally entered during QCette setup.) Confirm that the SN displayed matches the SN printed on the QCette plastic housing and press ENTER. The software requires that the serial number is entered in the correct format: six numeric characters (e.g., 006460). Enter all leading zeros.



```
fFN MAIN MENU
1-TEST PATIENT
2-SET CALIBRATION
3-DAILY QC ↓
```



```
DAILY QC
USER ID
>JOHN SMITH
ENTER-CONFIRM
```



```
DAILY QC
ENTER QCette SN
>006460
ENTER-CONFIRM
```


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 ESC. Either setup a new QCette, or re-do Daily QC with the correct QCette.

```
QCette SN CHANGED
NNNNNN
SETUP ANALYZER CTL
ESC-MAIN MENU
```

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

```
REMOVE CASSETTE

PRESS ENTER
TO CONTINUE
```

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

```
INSERT QCette

ENTER-CONTINUE
```

This message will be displayed if the QCette is not inserted. Press ENTER to continue.

```
QCette NOT
INSERTED

ENTER-CONTINUE
```

A 30-second timer starts during which time this message flashes and the analyzer beeps. Insert the QCette and press ENTER.

INSERT QCette
ENTER-CONTINUE

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

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

TEST WARNING: This message will be displayed if ESC was pressed during testing. Lines 1 and 2 will flash prompting the user to select ENTER to continue test, or ESC to end test. This message will hold for 5 seconds and then revert back to its respective screen.

**ARE YOU SURE YOU
WANT TO CANCEL TEST**
ENTER-CONTINUE
ESC-MAIN MENU

QCette Data Record — This record will be displayed on three screens. Each screen can be accessed by using the ← and → keys. The complete record will be printed automatically if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

QCette results are SYSTEM PASS or SYSTEM FAIL. The analyzer displays the PASS or FAIL result and the fFN concentration for each QCette level (LVL1 and LVL2).

A FAIL result should be repeated. (See Section 7, Troubleshooting, Items 9 and 10.)

```
QCette
03:00 PM 10/26/13
SYSTEM: PASS
USER: JOHN SMITH →
```

```
LVL1: PASS 20 ng/mL
LVL2: PASS 179 ng/mL
QCette SN:006460 ←→
```

```
CAL CODE:95HYA-76YTT
ANALYZER ID:G0237

ESC-MAIN MENU ←
```

Display and Printout

```
-----
HOLOGIC Rapid fFN®
-----
Rapid fFN 10Q QCette
SYSTEM: PASS
TIME: 03:00 PM DATE: 10/26/13
QCette LEVEL 1: PASS [ 20 ng/mL]
QCette LEVEL 2: PASS [179 ng/mL]
USER: JOHN SMITH
QCette SERIAL#: 006460
CALIBRATION CODE: 95HYA-76YTT
ANALYZER ID: G0237
-----
```

LIQUID CONTROLS

Option 8 on the Main Menu screen allows the user to run the LIQUID CONTROLS.

The USER ID must be entered to proceed to the next step. Press ENTER to accept the ID. This field will accept 15 alpha or numeric characters.

The CASSETTE LOT# must be entered to proceed to the next step. For convenience, the last 2 numbers only can be entered if the lot has not changed. The CASSETTE LOT# is located on the cassette pouch. The software requires that the lot number is entered in the correct format: one alpha character followed by four numeric characters (e.g., L1002).

fFN MAIN MENU
7-TEST COUNTS
8-LIQUID CONTROLS
9-USAGE REPORT
↓

RUN CONTROL
USER ID
>JOHN SMITH
ENTER-CONFIRM

RUN CONTROL
CASSETTE LOT #
>L1002
ENTER-ACCEPT

The analyzer automatically compares the CASSETTE LOT# used to set calibration with the CASSETTE LOT # used for testing controls. If the lot numbers do not match, the test process cannot continue. When this occurs, the cassette lot number used for calibration will be displayed, and the user is prompted to recalibrate the system.

```
CASSETTE LOT CHANGED
CALIBRATE SYSTEM
L1002
ESC-MAIN MENU
```

From the CONTROL TEST MENU, select 1-LEVEL 1 control or 2-LEVEL 2 control.

```
CONTROL TEST MENU
1-LEVEL 1
2-LEVEL 2
```

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

```
LEVEL 1 CONTROL LOT #
>M1023

ENTER-CONFIRM
```

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

```
REMOVE CASSETTE

PRESS ENTER
TO CONTINUE
```

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

INSERT CASSETTE
PRESS ENTER
TO CONTINUE

This message will be displayed if a cassette is not inserted. Press ENTER to return to the previous screen.

CASSETTE NOT
INSERTED

ENTER-CONTINUE

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

CHECKING CASSETTE

DO NOT REMOVE
CASSETTE

A 30-second timer starts during which time this message flashes and the analyzer beeps. Add 200 uL of control sample and **immediately** press ENTER.

ADD SAMPLE
AND IMMEDIATELY
PRESS ENTER

If the sample is not added and ENTER not pressed within allotted time, the test process cannot continue. This message will be displayed. Press ESC to return to the Main Menu. No record of the test will be held in memory.

SAMPLE NOT ADDED
WITHIN ALLOTTED TIME

ESC-MAIN MENU

Once the sample is added, the analyzer will begin a 7-minute incubation countdown. To abort the test, press ESC. Pressing ESC will terminate the test and the data will be lost.

TEST IN PROCESS
DO NOT REMOVE
CASSETTE

6 MIN 56 SEC

Upon completion of the 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.

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

TEST WARNING: This message will be displayed if ESC was pressed during testing. Lines 1 and 2 will flash prompting the user to select ENTER to continue test or ESC to end test. This message will hold for 5 seconds and then revert back to its respective screen. If the test is cancelled, a new cassette will be required to repeat the test.

CANCEL TEST?
ENTER-CONTINUE
ESC-MAIN MENU

6 MIN 37 SEC

Liquid Control Data Record - This record is displayed over three screens. Each screen can be accessed by using the ← and → keys. The complete record will be printed automatically if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

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 11 and 12.)

Rapid fFN 10Q
03:00 PM 10/26/13
LEVEL 1: M1023
fFN: 31 ng/mL →

USER:JOHN SMITH
ANALYZER QC: PASS
CASSETTE QC: PASS ← →

CAL CODE:95HYA-76YTT
CASSETTE LN:L1002
ANALYZER ID:G0237
ESC-MAIN MENU ←

Display and Printout

HOLOGIC Rapid fFN®

Rapid fFN 10Q LIQUID CTL RESULT
fFN CONC: 31 ng/mL
TIME: 03:00 PM DATE: 10/26/13

LIQUID CONTROL: LEVEL 1
CONTROL LN: M1023
USER: JOHN SMITH
CASSETTE LOT: L1002
CALIBRATION CODE: 95HYA-76YTT
ANALYZER ID: G0237

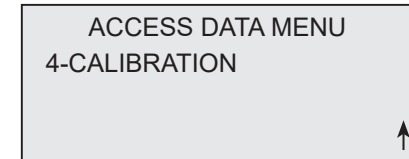
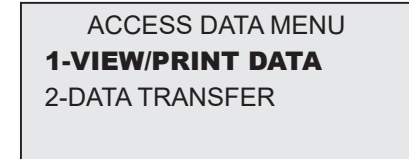
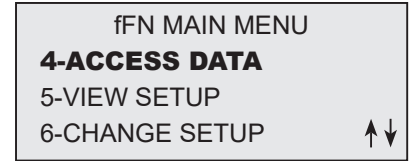
INTERNAL CONTROLS
ANALYZER QC: PASS
CASSETTE QC: PASS

ACCESS DATA — VIEW/PRINT DATA

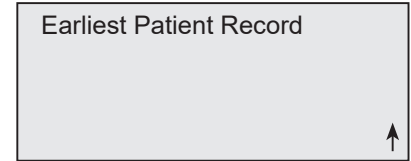
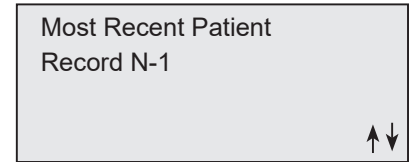
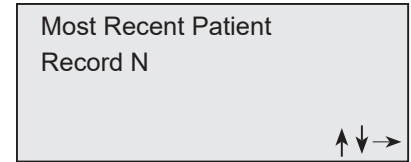
Option 4 on the Main Menu screen allows the user to ACCESS DATA stored in the analyzer.

Select option 1 on the ACCESS DATA MENU for VIEW/PRINT DATA.

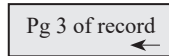
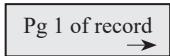
Select the category of data records to view/print. The categories are displayed over two screens. Each screen can be accessed by using ↓ and ↑ keys.



The most recent record for the category of data records selected will be displayed. PATIENT was chosen for this example. Use the ↑ and ↓ keys to view other records in the category.



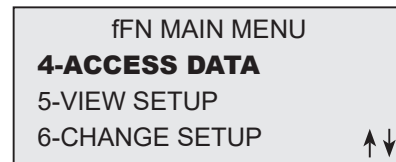
Use the ← and → keys to view pages within a record.



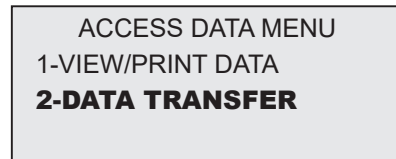
Printing the record — The record displayed may be printed by pressing the ENTER/PRINT key while in any of the three pages of the record. The full record will be printed on a single label.

ACCESS DATA — DATA TRANSFER

Option 4 on the Main Menu screen allows the user to ACCESS DATA for data transfer to a computer via an RS232 port.



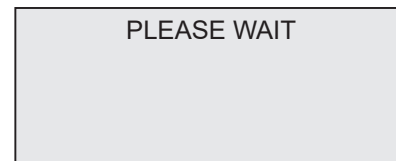
Select option 2 on the ACCESS DATA MENU for DATA TRANSFER.



Connect the appropriate end of the interface cable to the RS232 port (labeled DATA) of the analyzer. Connect the other end of the interface cable to the appropriate port of a computer.

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.

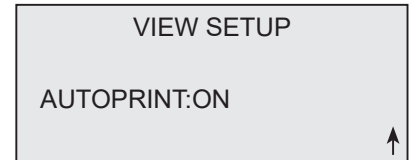
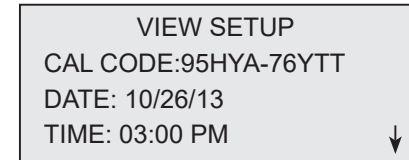
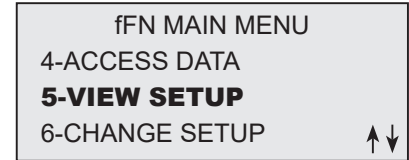
This message will be displayed while the data transfer is in process.



VIEW SETUP

Option 5 on the Main Menu screen allows the user to view current settings without editing them.

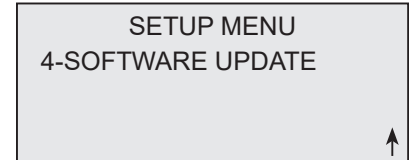
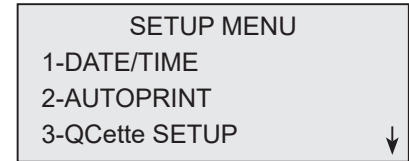
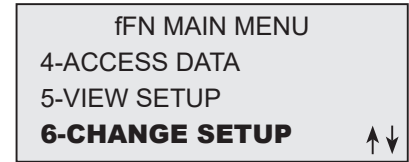
VIEW SETUP is displayed over two screens. Each screen can be accessed by using ↓ and ↑ keys.



CHANGE SETUP — DATE/TIME

Option 6 on the Main Menu screen allows the user to change the DATE/TIME, Autoprint, or to perform QCette Setup from the SETUP MENU. This option also allows Hologic Technical Support to update the software version.

Select option 1 on the SETUP MENU to change the DATE/TIME.



Enter the date at the cursor position on the SET DATE display.
Select the preferred format and press ENTER to continue.

Single digit months and days must be preceded by a zero (e.g.,
August 10, 2013 will be entered as 08/10/13). Use the ← key to delete
incorrect entries. Press ENTER to accept.

Select **1** for 12 HOUR (AM/PM) format or **2** for 24 HOUR format on the
SET TIME display.

SET DATE FORMAT
1-MM/DD/YY
2-DD/MM/YY

MM/DD/YY
FORMAT SET

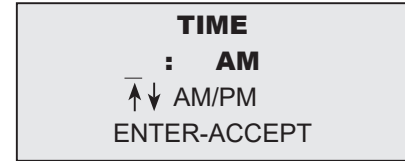
ENTER-CONTINUE

SET DATE
MM/DD/YY
>08/10/13
ENTER-ACCEPT

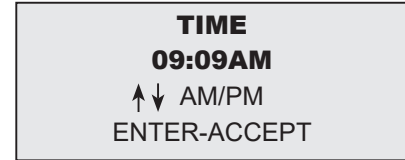
SET TIME
1-12 HOUR
2-24 HOUR

12 Hour (AM/PM) Format

Enter the time at the cursor position on the TIME display.

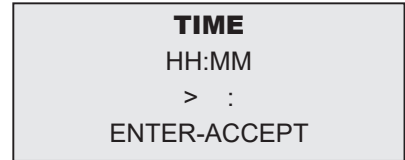


Single digit hours or minutes must be preceded by a zero (e.g., 9:09am must be entered as 09:09AM). Use the ← key to delete incorrect entries. Use the ↑↓ keys to choose AM/PM. Press ENTER to accept and return to the SETUP MENU.

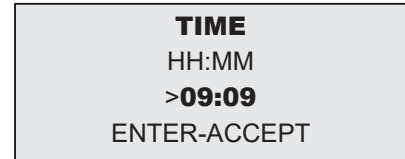


24 Hour Format

Enter the time at the cursor position on the TIME display.



Single digit hours or minutes must be preceded by a zero (e.g., 9:09am must be entered as 09:09). Use the ← key to delete incorrect entries. Press ENTER to accept and return to the SETUP MENU.



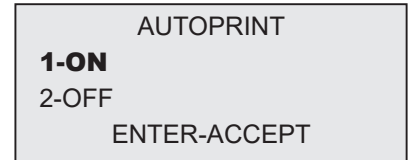
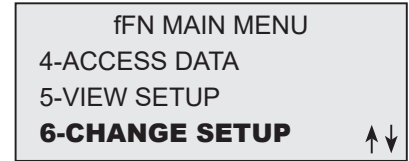
CHANGE SETUP — AUTOPRINT

Option 6 on the Main Menu screen allows the user to change the DATE/TIME, AUTOPRINT or to perform QCette SETUP from the SETUP MENU. This option also allows Hologic Technical Support to update the software version.

Select option 2 on the SETUP MENU to change AUTOPRINT.

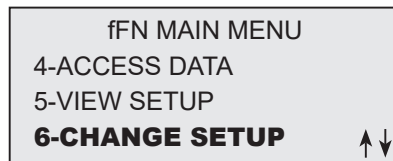
Autoprint automatically prints test results when set in the ON position. When set in the OFF position, printouts may be obtained by pressing the PRINT/ENTER key.

The current setting will be flashing. Select 1-ON or 2-OFF. Press ENTER to accept and return to the SETUP MENU.

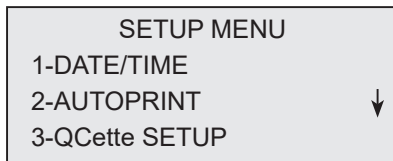


CHANGE SETUP — Rapid fFN 10Q QCette® SETUP

Option 6 on the Main Menu screen allows the user to change the Date/Time, Autoprint, or to perform QCette SETUP from the SETUP MENU. This option also allows Hologic Technical Support to update the software version.



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 a quality control device.



Select option 3 on the SETUP MENU to begin QCette SETUP.

The USER ID must be entered to proceed to the next step. Press ENTER to accept the ID. This field will accept 15 alpha or numeric characters.

```
QCette SETUP
  USER ID
>JOHN SMITH
  ENTER-CONFIRM
```

The QCette SN (serial number) must be entered to proceed to the next step. 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., 004640). Enter all leading zeros.

```
QCette SETUP
  ENTER QCette SN
>004640
  ENTER-CONFIRM
```

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

```
REMOVE CASSETTE

PRESS ENTER
TO CONTINUE
```

The analyzer then prompts the user to insert the QCette and press ENTER. A two-minute timer starts during which time this message flashes and the analyzer beeps. Insert the QCette and press ENTER.

```
INSERT QCette

ENTER-CONTINUE
```

This message will be displayed if the QCette is not inserted. Press ENTER to continue. Then insert the QCette and press ENTER.

CASSETTE NOT
INSERTED

ENTER-CONTINUE

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 ESC.

INITIALIZING QCette

DO NOT REMOVE
CASSETTE

TEST WARNING: This message will appear if ESC was pressed during testing. Lines 1 and 2 will flash prompting the user to select ENTER to continue test, or ESC to end test. This message will hold for 5 seconds and then revert back to its respective screen.

**ARE YOU SURE YOU
WANT TO CANCEL TEST**

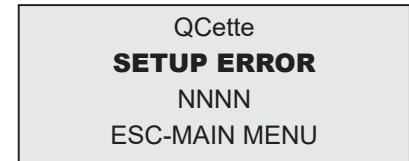
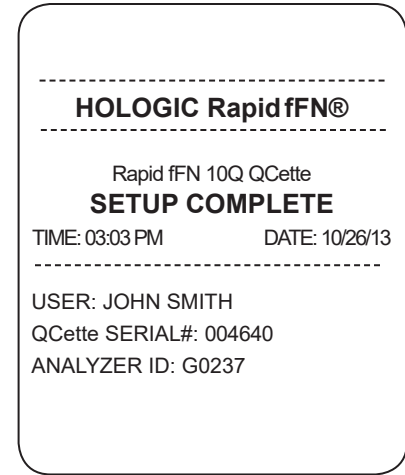
ENTER-CONTINUE
ESC-MAIN MENU

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.



Display and Printout

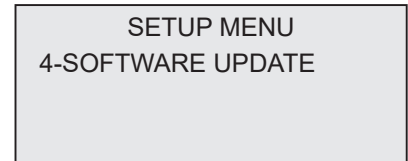
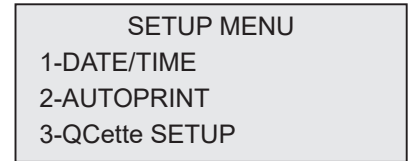
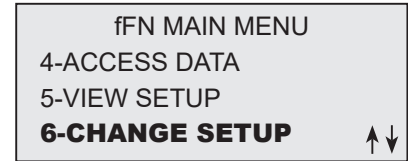
This message will be displayed if the QCette Setup is not completed. SETUP ERROR indicates that the performance criteria of the analyzer have not been established. If the QCette setup error occurs, see Section 7, Troubleshooting, Item 9.



CHANGE SETUP - SOFTWARE UPDATE

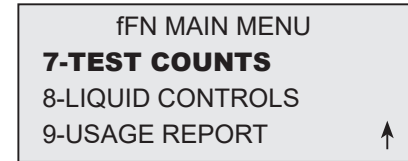
Option 6 on the Main Menu screen allows the user to change the DATE/TIME, Autoprint, or to perform QCette Setup from the SETUP MENU. This option also allows Hologic Technical Support to update the software version.

Software updates to the Rapid fFN 10Q System can only be performed by Hologic Technical Support.

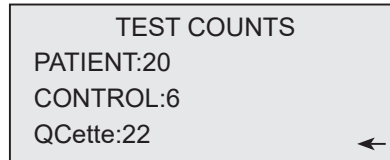
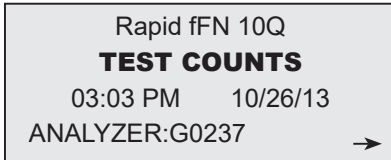


TEST COUNTS

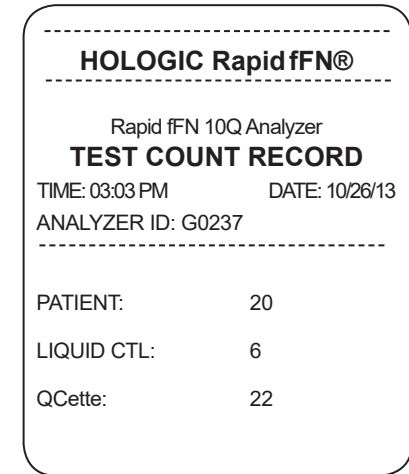
Option 7 on the Main Menu screen allows the user to view the number of tests by category that were performed on the analyzer and automatically print a Test Counts Report (TCR).



TEST COUNTS are displayed over two screens. Each screen can be accessed by using the ← and → keys.



Display and Printout



USAGE REPORT

Option 9 on the Main Menu allows the user to view or print a summary of patient tests performed for each month in the past 12 months (rolling calendar).

USAGE REPORT is displayed over two screens. Each screen can be accessed by using the ← and → keys.

The total number of patient tests is displayed.

Print the report by pressing the PRINT button. The second screen scrolls forward and back among the months using the ↑ and ↓ keys to display each month.

DATE: 10/26/13	→	
ANALYZER:G0237		
RESULTS	INV	TOTAL
0049	002	00051

FEB 2012		
RESULTS	INV	TOTAL
000	001	00009
		← ↑ ↓

Display and Printout

fFN MAIN MENU	
7-TEST COUNTS	
8-LIQUID CONTROLS	
9-USAGE REPORT	↑

USAGE REPORT: S/N G0237G10DP			
TIME: 03:12 PM		DATE: 10/26/13	
MONTH	RESULTS	INV	TOTAL
MAR	0004	000	00004
FEB	0008	001	00009
JAN	0007	000	00007
DEC	0013	000	00013
NOV	0005	000	00005
OCT	0012	001	00013
SEP	0000	000	00000
AUG	0000	000	00000
JUL	0000	000	00000
JUN	0000	000	00000
MAY	0000	000	00000
APR	0000	000	00000
TTL	00049	002	00051

SECTION 5 — CARE OF THE ANALYZER

GENERAL CLEANING

Keep the analyzer free of dust. If needed, clean the exterior 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 display and keypad.

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 membrane keypad.

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

- 10% Bleach in water
- 75% Isopropyl Alcohol
- General laboratory cleaning detergent with disinfectant properties

SECTION 6 — PRINTER

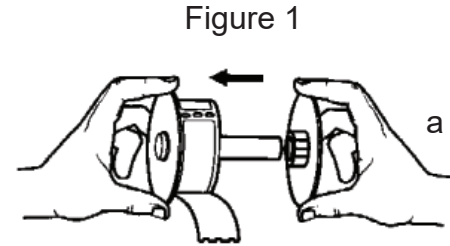
LOADING PRINTER LABELS

Refer to Section 2, Installation, for instructions on connecting the printer to the Rapid fFN® 10Q Analyzer.

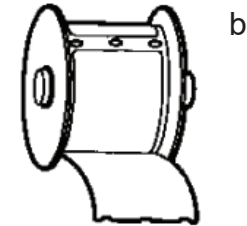
Note: DO NOT install any of the Dymo Label software that is packaged with the printer.

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.



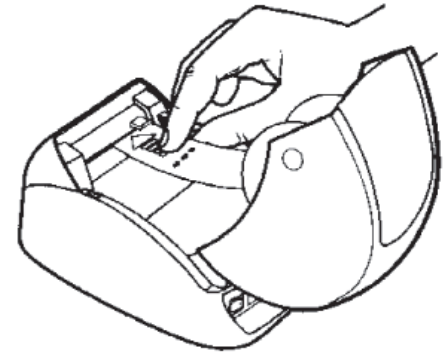
6. Ensure the power cord is connected. Turn on the printer by plugging it in to a power outlet. The power light will flash and the printer motor will run as it looks for labels to feed.
7. Holding the spool of labels in one hand, use the other hand to feed the free end of the roll into the feed slot 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).

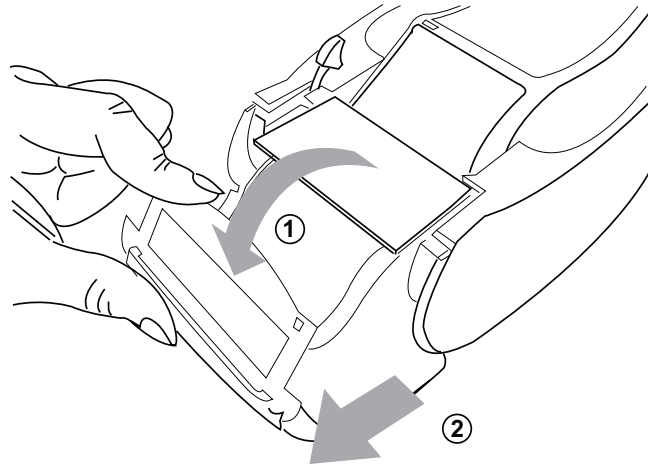
CLEARING LABEL JAMS

Note: To prevent label jams, tear off print outs 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 Loading Printer Labels 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 Rapid fFN 10Q 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, Inc. Technical Support for any questions related to the performance of your Rapid fFN 10Q 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 plugged into a grounded AC electrical outlet. Ensure analyzer ON/OFF switch is in ON position.
2	Error Code is displayed when analyzer is first turned on.	Analyzer	Turn analyzer off and back on to reinitialize the system. If the Error Code persists, refer to Error/Invalid Code table.

ITEM	PROBLEM	SOURCE	SOLUTION
3	Analyzer display screen is frozen on the INITIALIZING screen.	Thumb drive in the USB port	<p>Turn off the analyzer.</p> <p>Remove the thumb drive from the USB port.</p> <p>Turn on the analyzer.</p> <p>Proceed with testing.</p>
4	Analysis process is interrupted and/or unusual characters appear on display screen, and the analyzer does not respond to keypad inputs.	Momentary power interruption	<p>Disconnect the printer power cord from the electrical outlet.</p> <p>Turn off the analyzer.</p> <p>Reconnect the printer power cord to the electrical outlet.</p> <p>Turn on the analyzer.</p> <p>Proceed with testing.</p>

ITEM	PROBLEM	SOURCE	SOLUTION
5	Printer fails to print	<p>Printer Power Cord/ Power Adapter</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 power adapter and the power adapter is firmly connected to the printer. The power indicator light should be on.</p> <p>Ensure printer power cord is plugged into a grounded AC electrical outlet. Disconnect and reconnect the power cord. Be sure the power indicator light is 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>Plug the printer in. Turn the analyzer off and back on. Recall the test result on the analyzer display screen (4-ACCESS DATA). Press PRINT/ENTER on the analyzer to print the result.</p>

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

ITEM	PROBLEM	SOURCE	SOLUTION
9	Rapid fFN 10Q QCette failed to complete setup.	Rapid fFN 10Q 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. If QCette setup is complete, run 3-Daily QC, followed by 8-Liquid Controls.</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
10	Rapid fFN 10Q QCette failed during daily quality control.	Rapid fFN 10Q 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 Daily QC printout.</p> <p>Ensure QCette is clean and not damaged. The QCette may be cleaned with canned air.</p> <p>Run 3-Daily QC. If this passes, no further troubleshooting is required.</p> <p>If Daily QC fails, perform 6-3-QCette setup. If QCette setup is complete, run 3-Daily QC, followed by 8-Liquid Controls. If both pass, no further troubleshooting is required.</p> <p>If Daily QC fails a second time, call Technical Support.</p>

ITEM	PROBLEM	SOURCE	SOLUTION
11	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
12	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 menu 3-Daily QC. If the Daily QC result is Pass, retest the control on a new cassette. If both pass, no further troubleshooting is required.</p> <p>If the Daily QC result is Fail, call Technical Support.</p>
		Internal Controls Analyzer QC: Pass Cassette QC: Fail	<p>Verify that 200 uL 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
13	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 Daily 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 uL 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	Internal Controls Cassette QC Failure	Refer to Troubleshooting Items 12 and 13.
142A	Dark Count Out of Range	Turn analyzer off and back on to reinitialize the system. Retest Daily QC. If Daily QC passes, continue with normal operation. If Daily QC fails, contact Technical Support.
142B	Sensor Error	Turn analyzer off and back on to reinitialize the system. Retest Daily QC. If Daily QC passes, continue with normal operation. If Daily QC fails, contact Technical Support.
622	Possible Voltage Problem	Turn analyzer off and back on to reinitialize the system. Retest Daily QC. If Daily QC passes, continue with normal operation. If Daily QC fails, contact Technical Support.
720 721	Possible Motor Problem	Turn analyzer off and back on to reinitialize the system. Retest Daily QC. If Daily QC passes, continue with normal operation. If Daily QC fails, contact Technical Support.

If analyzer errors persist or recur, call Technical Support.

ERROR CODE	DEFINITION	TROUBLESHOOTING PROCEDURE
1436	Low Input Voltage Detected	The correct power adapter is required. Ensure the 10Q power adapter is being used with the analyzer. Contact Technical Support.
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 9).
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 12 and 13. Retest Daily QC. If Daily QC passes, continue with normal operation. If Daily QC fails, contact Technical Support.
OE22, OE23	Possible Optics Problem	Turn the analyzer off and back on to reinitialize the system. Retest Daily QC. If Daily QC passes, continue with normal operation. If Daily QC fails, contact Technical Support.
Other Codes		Call Technical Support.

If analyzer errors persist or recur, call Technical Support.

SECTION 8 — SERVICE AND WARRANTY

TECHNICAL SUPPORT

Analyzer

The Rapid fFN 10Q 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, call Hologic, Inc. Technical Support.

Printer

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

CONTACT INFORMATION

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
www.hologic.com

TECHNICAL SUPPORT (USA/Canada)

Tel: 1-800-442-9892

Fax: 1-508-229-2795

TECHNICAL SUPPORT (Outside the USA and Canada)

Tel:

Asia	+852 3526 0718	Netherlands:	0800 022 6782
Australia:	+61 2 9888 8000	Norway:	800 155 64
Austria:	0800 291 919	Portugal:	800 841 034
Belgium:	0800 773 78	Spain:	900 994 197
Denmark:	8088 1378	South Africa:	0800 980 731
Finland:	0800 114 829	Sweden:	020 797 943
France:	0800 913 659	Switzerland:	0800 298 921
Germany:	0800 183 0227	UK:	0800 032 3318
Ireland (Rep):	1 800 554 144	Rest of the world:	00800.800.442.9892
Italy:	800 786 308		

Intl Fax number: 0041.21.633.39.10

email: intltechsupport@hologic.com

Replacement Parts

Item	Catalog Number
Printer Labels	52660-001
Rapid fFN 10Q QCette	PRD-01021
Rapid fFN 10Q Liquid Controls Kit	PRD-01019
Specimen Collection Kit	PRD-01020
Rapid fFN Cassettes, 26-pack box	PRD-01018
Rapid fFN 10Q System User Manual	MAN-06422-001

Contact fFN Customer Service to order replacement parts.

CONTACT INFORMATION

fFN CUSTOMER SERVICE (USA/Canada only)

Tel: 1-800-442-9892

Fax: 1-508-229-2860

fFN 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 00800-800-442-9892

Rapid fFN 10Q® System

Analyzer Serial Number _____

Printer Serial Number _____

Shipment Date _____

MANUFACTURER'S WARRANTY

Hologic, Inc. warrants to the original purchaser that this system will be free from defects in materials and workmanship for a period of one (1) year from shipment date (except as noted below). During the stated one-year period, Hologic, Inc. shall, at its option, replace with a new unit, reconditioned unit, or repair at no charge a unit that is found to be defective.

This warranty is subject to the following exceptions and limitations:

1. This warranty is limited to repair or replacement due to defects in parts or workmanship. Hologic, Inc. shall not be required to make any repairs or replacements which are necessitated by abuse, accidents, alterations, misuse, neglect, maintenance by other than Hologic, Inc., or failure to operate the system in accordance with manufacturer's instructions. Further, Hologic, Inc. assumes no liability for malfunction or damage to the system caused by the use of reagents other than reagents manufactured or recommended by Hologic, Inc.

2. Hologic, Inc. reserves the right to make changes in the design of this system without obligation to incorporate such changes into previously manufactured systems.

Disclaimer of Warranties

THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESS OR IMPLIED (EITHER IN FACT OR BY OPERATION OF LAW) INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE WHICH ARE EXPRESSLY EXCLUDED, AND IS THE ONLY WARRANTY GIVEN BY Hologic, Inc.

Limitations of Liability

IN NO EVENT SHALL Hologic, Inc. BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF Hologic, Inc. HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service and extended warranty service, purchaser must contact the Technical Support Department of Hologic, Inc. by calling 1-800-442-9892 for assistance and/or instructions for obtaining repair of the system.