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

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Marlborough, MA 01752 USA
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   Netherlands: 0800 022 6782
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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.

The Hologic logo, Rapid fFN®10Q, and Rapid fFN®10Q QCette are trademarks and/or registered trademarks of Hologic, Inc.

Printed in the USA

AW-19875-001 Rev. 001 8-2019
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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

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
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<tr>
<td>Power Supply</td>
<td>UL 15 VDC listed power supply</td>
</tr>
<tr>
<td>Memory Capacity</td>
<td>50 Calibration Records</td>
</tr>
<tr>
<td></td>
<td>50 QCette Records</td>
</tr>
<tr>
<td></td>
<td>50 Control Records</td>
</tr>
<tr>
<td></td>
<td>1000 Patient Records</td>
</tr>
<tr>
<td>Display</td>
<td>4 lines</td>
</tr>
<tr>
<td></td>
<td>20 characters per line</td>
</tr>
<tr>
<td></td>
<td>Alphanumeric 5 x 8 matrix Supertwist LCD</td>
</tr>
<tr>
<td></td>
<td>Black characters with gray background</td>
</tr>
<tr>
<td>Keypad</td>
<td>3.5 x 4.5 inches</td>
</tr>
<tr>
<td></td>
<td>Tactile membrane</td>
</tr>
<tr>
<td></td>
<td>Alphanumeric keys</td>
</tr>
</tbody>
</table>
| **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:

<table>
<thead>
<tr>
<th>![Symbol Image]</th>
<th>Do not dispose in municipal waste.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Contact Hologic (see below) for information regarding proper disposal.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Corporate Headquarters</th>
<th>Hologic, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>250 Campus Drive</td>
</tr>
<tr>
<td></td>
<td>Marlborough, MA 01752 USA</td>
</tr>
<tr>
<td></td>
<td>Tel: (USA and Canada)</td>
</tr>
<tr>
<td></td>
<td>1-800-442-9892</td>
</tr>
<tr>
<td></td>
<td>1-508-263-2900</td>
</tr>
<tr>
<td></td>
<td>Fax: 1-508-263-2967</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Authorized Representative - Outside of U.S.</th>
<th>Hologic BVBA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Da Vincilaan 5</td>
</tr>
<tr>
<td></td>
<td>1930 Zaventem</td>
</tr>
<tr>
<td></td>
<td>Belgium</td>
</tr>
</tbody>
</table>
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.
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.

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.
# OVERVIEW OF Rapid fFN 10Q ANALYZER MAIN MENU

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

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<th>Upon System Installation</th>
<th>Routine Daily Use</th>
<th>New Lot of Cassettes</th>
</tr>
</thead>
<tbody>
<tr>
<td>6  Set Date /Time</td>
<td>3  Daily QC</td>
<td>2  Set Calibration</td>
</tr>
<tr>
<td>6  Select Autoprint On/Off</td>
<td>1  Test Patient</td>
<td>3  Daily QC</td>
</tr>
<tr>
<td>6  QCette Setup</td>
<td>View/Print Results</td>
<td>8  Liquid Controls</td>
</tr>
<tr>
<td>2  Set Calibration</td>
<td></td>
<td>1  Test Patient</td>
</tr>
<tr>
<td>3  Daily QC</td>
<td></td>
<td>View/Print Results</td>
</tr>
<tr>
<td>8  Liquid Controls</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1  Test Patient</td>
<td>View/Print Results</td>
<td></td>
</tr>
<tr>
<td>View/Print Results</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## KEY TO USER ENTRY FIELDS

<table>
<thead>
<tr>
<th>Field</th>
<th>Length</th>
<th>Required Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>User ID</td>
<td>Up to 15 characters</td>
<td>Any combination of letters and numbers. An entry must be made.</td>
</tr>
<tr>
<td>Patient ID</td>
<td>Up to 16 characters</td>
<td>Any combination of letters and numbers. An entry must be made.</td>
</tr>
<tr>
<td>Cassette Lot Number</td>
<td>5 characters</td>
<td>ANNNN where A=Alpha, N=Number. Enter the lot number exactly as it appears on the cassette pouch.</td>
</tr>
<tr>
<td>Calibration Code</td>
<td>10 characters</td>
<td>Enter the cal code exactly as it appears on the cassette box.</td>
</tr>
<tr>
<td>Liquid Control Lot Number</td>
<td>Up to 12 characters</td>
<td>Enter the liquid control lot number exactly as it appears on the bottle. An entry must be made.</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>PATIENT ID</th>
<th>PATIENT ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;AB3</td>
<td>&gt;ABE</td>
</tr>
<tr>
<td>ENTER - ACCEPT</td>
<td>ENTER - ACCEPT</td>
</tr>
</tbody>
</table>

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.
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.
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.

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

Display and Printout

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 ←

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.
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.

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.

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

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

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

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.
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.

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.

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 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.

**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.

![](image)

**Display and Printout**

Patient results are displayed as the fFN concentration in ng/mL, or INVALID.
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 QCtte® for the first time, QCtte SETUP must be performed. See page 4-29. Refer to the Rapid fFN 10Q QCtte 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 QCtte.

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 QCtte SN (serial number) is displayed. (It was originally entered during QCtte setup.) Confirm that the SN displayed matches the SN printed on the QCtte 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.

<table>
<thead>
<tr>
<th>fFN MAIN MENU</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-TEST PATIENT</td>
</tr>
<tr>
<td>2-SET CALIBRATION</td>
</tr>
<tr>
<td><strong>3-DAILY QC</strong></td>
</tr>
</tbody>
</table>

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

| DAILY QC |
| ENTER QCtte 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.

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

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

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

QCette SN CHANGED
NNNNNN
SETUP ANALYZER CTL
ESC-MAIN MENU

REMOVE CASSETTE
PRESS ENTER TO CONTINUE

INSERT QCette
ENTER-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.

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 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.
**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.)

**Display and Printout**

<table>
<thead>
<tr>
<th>QCette</th>
<th>LVL1: PASS 20 ng/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>03:00 PM</td>
<td>LVL2: PASS 179 ng/mL</td>
</tr>
<tr>
<td>10/26/13</td>
<td>QCette SN:006460</td>
</tr>
<tr>
<td>SYSTEM: PASS</td>
<td>USER: JOHN SMITH</td>
</tr>
<tr>
<td>USER: JOHN SMITH</td>
<td></td>
</tr>
<tr>
<td>CAL CODE:95HYA-76YTT</td>
<td>ANALYZER ID:G0237</td>
</tr>
</tbody>
</table>

**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).
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.

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

Enter the control lot number and press ENTER. 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 ENTER.
The analyzer then prompts the user to insert the cassette and press ENTER.

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

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

A 30-second timer starts during which time this message flashes and the analyzer beeps. Add 200 µL of control 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.

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.

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 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.
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.)
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.
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.

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.

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

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

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.

**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.
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.

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

Rapid fFN 10Q
TEST COUNTS
03:03 PM 10/26/13
ANALYZER:G0237

TEST COUNTS
PATIENT:20
CONTROL:6
QCette:22

HOLOGIC Rapid fFN®
Rapid fFN 10Q Analyzer
TEST COUNT RECORD
TIME: 03:03 PM DATE: 10/26/13
ANALYZER ID: G0237

PATIENT: 20
LIQUID CTL: 6
QCette: 22
**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).

**Display and Printout**

---

**DATE: 10/26/13**
**ANALYZER: G0237**

**RESULTS** | **INV** | **TOTAL**
--- | --- | ---
0049 | 002 | 00051

**FEB 2012**

**RESULTS** | **INV** | **TOTAL**
--- | --- | ---
000 | 001 | 00009

**TIME: 03:12 PM**
**DATE: 10/26/13**

**MONTH** | **RESULTS** | **INV** | **TOTAL**
--- | --- | --- | ---
MAR | 00004 | 000 | 00004
FEB | 00008 | 001 | 00009
JAN | 00007 | 000 | 00007
DEC | 00013 | 000 | 00013
NOV | 00005 | 000 | 00005
OCT | 00012 | 001 | 00013
SEP | 00000 | 000 | 00000
AUG | 00000 | 000 | 00000
JUL | 00000 | 000 | 00000
JUN | 00000 | 000 | 00000
MAY | 00000 | 000 | 00000
APR | 00000 | 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.
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.

<table>
<thead>
<tr>
<th>ITEM</th>
<th>PROBLEM</th>
<th>SOURCE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Analyzer display screen is blank.</td>
<td>Analyzer Power Cord and/or Adapter</td>
<td>Ensure analyzer power cord is firmly connected to analyzer.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ON/OFF switch</td>
<td>Ensure analyzer power adapter is plugged into a grounded AC electrical outlet.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ensure analyzer ON/OFF switch is in ON position.</td>
</tr>
<tr>
<td>2</td>
<td>Error Code is displayed when analyzer is first turned on.</td>
<td>Analyzer</td>
<td>Turn analyzer off and back on to reinitialize the system.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>If the Error Code persists, refer to Error/Invalid Code table.</td>
</tr>
<tr>
<td>ITEM</td>
<td>PROBLEM</td>
<td>SOURCE</td>
<td>SOLUTION</td>
</tr>
<tr>
<td>------</td>
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</tr>
</tbody>
</table>
| 3    | Analyzer display screen is frozen on the INITIALIZING screen. | Thumb drive in the USB port | Turn off the analyzer.  
Remove the thumb drive from the USB port.  
Turn on the analyzer.  
Proceed with testing. |
| 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 | 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.  
Proceed with testing. |
<table>
<thead>
<tr>
<th>ITEM</th>
<th>PROBLEM</th>
<th>SOURCE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Printer fails to print</td>
<td>Printer Power Cord/ Power Adapter</td>
<td>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. 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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>USB Cable</td>
<td>Ensure USB cable is connected to the printer and the analyzer.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Printer Labels</td>
<td>Ensure printer is not out of printer labels. To order printer labels, contact Customer Service.</td>
</tr>
<tr>
<td></td>
<td>Printer not plugged in when test was run.</td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>ITEM</td>
<td>PROBLEM</td>
<td>SOURCE</td>
<td>SOLUTION</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>6</td>
<td>Printer output in unusual font.</td>
<td>Printer</td>
<td>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.</td>
</tr>
<tr>
<td>7</td>
<td>Analyzer turned off after calibration, or power failure occurred after calibration.</td>
<td>Power</td>
<td>The calibration remains in memory. Reset calibration only if prompted by analyzer.</td>
</tr>
<tr>
<td>8</td>
<td>Cassette or QCette cannot be removed from the analyzer.  <strong>(Note: do not try to force or pry it out of the analyzer.)</strong></td>
<td>Analyzer</td>
<td>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.</td>
</tr>
<tr>
<td>ITEM</td>
<td>PROBLEM</td>
<td>SOURCE</td>
<td>SOLUTION</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>9</td>
<td>Rapid fFN 10Q QCette failed to complete setup.</td>
<td>Rapid fFN 10Q QCette or Analyzer</td>
<td>Turn analyzer off and back on to reinitialize the system. Ensure QCette is clean and not damaged. The QCette can be cleaned with canned air. Repeat QCette setup as described in Section 4. If QCette setup is complete, run 3-Daily QC, followed by 8-Liquid Controls. Do not bump or jar analyzer or QCette during the test. If the QCette setup fails a second time, call Technical Support.</td>
</tr>
<tr>
<td>ITEM</td>
<td>PROBLEM</td>
<td>SOURCE</td>
<td>SOLUTION</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>10</td>
<td>Rapid fFN 10Q QCette failed during daily quality control.</td>
<td>Rapid fFN 10Q QCette or Analyzer</td>
<td>Turn analyzer off and back on to reinitialize the system. Confirm that the QCette serial number on the device matches the serial number programmed in the analyzer, indicated on the Daily QC printout. Ensure QCette is clean and not damaged. The QCette may be cleaned with canned air. Run 3-Daily QC. If this passes, no further troubleshooting is required. 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. If Daily QC fails a second time, call Technical Support.</td>
</tr>
<tr>
<td>ITEM</td>
<td>PROBLEM</td>
<td>SOURCE</td>
<td>SOLUTION</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>11</td>
<td>Liquid control result is outside the range of acceptable results.</td>
<td>Liquid Control</td>
<td>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. Verify the control has not expired, and is neither cloudy nor discolored. If contamination of the controls is suspected, open a new box of controls. 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. If the control result is outside the range of acceptable results a second time, call Technical Support.</td>
</tr>
<tr>
<td>ITEM</td>
<td>PROBLEM</td>
<td>SOURCE</td>
<td>SOLUTION</td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------------------</td>
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</tr>
<tr>
<td>12</td>
<td>Invalid liquid control test result.</td>
<td>Internal Controls Analyzer QC: Fail Cassette QC: Pass</td>
<td>Refer to Error/Invalid Code table. Turn analyzer off and back on to reinitialize the system. 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. If the Daily QC result is Fail, call Technical Support. Verify that 200 uL of control was dispensed. 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. Do not bump or jar the analyzer or the cassette during the test. If control is invalid a second time, call Technical Support.</td>
</tr>
<tr>
<td>ITEM</td>
<td>PROBLEM</td>
<td>SOURCE</td>
<td>SOLUTION</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------</td>
<td>---------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>13</td>
<td>Invalid patient test result</td>
<td>Internal Controls Analyzer QC: Fail Cassette QC: Pass</td>
<td>Refer to Error/Invalid Code table.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Turn analyzer off and back on to reinitialize the system.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rerun the Daily QC. If the result is Pass, retest the sample on a new cassette. If both pass, no further troubleshooting is required.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>If the Patient Test result is Invalid, call Technical Support.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Internal Controls Analyzer QC: Pass Cassette QC: Fail</td>
<td>Verify that 200 uL of sample was dispensed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Review the Rapid fFN 10Q Cassette Kit directional insert to ensure the correct procedure was followed. Repeat the test on a new cassette.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Retest the sample on a new cassette. If the problem is not corrected, contact the physician and recommend recollection in 24 hours.</td>
</tr>
</tbody>
</table>
## ERROR/INVALID CODES

<table>
<thead>
<tr>
<th>ERROR CODE</th>
<th>DEFINITION</th>
<th>TROUBLESHOOTING PROCEDURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>003, 004, 007, 020, 024, 100, 103, 104, 107</td>
<td>Internal Controls Cassette QC Failure</td>
<td>Refer to Troubleshooting Items 12 and 13.</td>
</tr>
<tr>
<td>142A</td>
<td>Dark Count Out of Range</td>
<td>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.</td>
</tr>
<tr>
<td>142B</td>
<td>Sensor Error</td>
<td>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.</td>
</tr>
<tr>
<td>622</td>
<td>Possible Voltage Problem</td>
<td>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.</td>
</tr>
<tr>
<td>720 721</td>
<td>Possible Motor Problem</td>
<td>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.</td>
</tr>
</tbody>
</table>

If analyzer errors persist or recur, call Technical Support.

Rapid fFN 10Q System User Manual
Section 7 — Troubleshooting
<table>
<thead>
<tr>
<th>ERROR CODE</th>
<th>DEFINITION</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1436</td>
<td>Low Input Voltage Detected</td>
<td>The correct power adapter is required. Ensure the 10Q power adapter is being used with the analyzer. Contact Technical Support.</td>
</tr>
<tr>
<td>OD24</td>
<td>Possible QCette Problem</td>
<td>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).</td>
</tr>
<tr>
<td>OE21</td>
<td>High Light Level</td>
<td>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.</td>
</tr>
<tr>
<td>OE22, OE23</td>
<td>Possible Optics Problem</td>
<td>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.</td>
</tr>
<tr>
<td>Other Codes</td>
<td></td>
<td>Call Technical Support.</td>
</tr>
</tbody>
</table>

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:**

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

**Intl Fax number:** 0041.21.633.39.10

**Email:** intltechsupport@hologic.com
Replacement Parts

<table>
<thead>
<tr>
<th>Item</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printer Labels</td>
<td>52660-001</td>
</tr>
<tr>
<td>Rapid fFN 10Q QCette</td>
<td>PRD-01021</td>
</tr>
<tr>
<td>Rapid fFN 10Q Liquid Controls Kit</td>
<td>PRD-01019</td>
</tr>
<tr>
<td>Specimen Collection Kit</td>
<td>PRD-01020</td>
</tr>
<tr>
<td>Rapid fFN Cassettes, 26-pack box</td>
<td>PRD-01018</td>
</tr>
<tr>
<td>Rapid fFN 10Q System User Manual</td>
<td>MAN-06422-001</td>
</tr>
</tbody>
</table>

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.