TLi System

User Manual

IMPORTANT: Read the entire manual before operating the TLi$_{IQ}$® System.

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Italy:	800 786 308	Intl Fax number:	0041.21.633.39.10

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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 of a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

> Reorient or relocate the receiving antenna.
> Increase the separation between the equipment and receiver.
> Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
> Consult the dealer or an experienced radio/television technician for help.

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:

EN61326-1	Electrical Equipment for Measurement, Control and Laboratory Use
EN55011	Radiated and Conducted Emissions
EN61010-1	Safety Requirements
EN61000-3-2	Harmonic Emissions
EN61000-3-3	Voltage Fluctuations
EN61000-4-2	Electrostatic Discharge
EN61000-4-4	Electrical Fast Transients
EN61000-4-5	Voltage Surges
EN61000-4-6	Conducted Immunity
EN61000-4-11	Voltage Interrupts

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:

	Do not dispose in municipal waste. Contact Hologic (see below) for information regarding proper disposal.
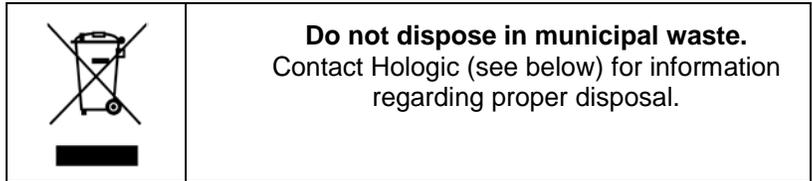
Reclamation
Hologic will provide for the collection and proper reclamation of electrical devices we provide to our customers. Hologic strives to reuse Hologic devices, subassemblies, and components whenever possible. When reuse is not appropriate, Hologic will ensure the waste material is properly disposed of.

Hologic Contact Information

Corporate Headquarters	HOLOGIC INC.
	250 CAMPUS DRIVE
	MARLBOROUGH, MA 01752 USA
	TEL: (USA and Canada)
	     1-888-PRETERM (1-888-773-8376)
	     1-800-442-9892
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Authorized Representative - Europe	HOLOGIC (UK) LIMITED UNIT 2, LINK 10 NAPIER WAY CRAWLEY, WEST SUSSEX RH10 9RA UNITED KINGDOM Tel: +44 1293 522080 FAX: +44 1293 528010

Symbols Used on the Instrument
The following symbols are used on this instrument:

⚠	Warning, refer to accompanying documents.	◢◣◢	Manufactured by
♻ (crossed out wheelie bin)	Waste Electrical and Electronic Equipment - contact Hologic for disposal of the instrument.	EC REP	Authorized Representative in the European Community
LOT	Lot	30°C / 18°C thermometer	Store between 18°C and 30°C
REF	Catalog number	IVD	For *in vitro* diagnostic testing

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SECTION I – INTRODUCTION

IVD

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

INTENDED USE

The Hologic TLi$_{IQ}$® System is intended to be used in conjunction with the Rapid fFN Cassette, the Rapid fFN Control Kit, and the TLi$_{IQ}$ QCette® for the detection of fetal fibronectin in cervicovaginal secretions. Refer to the directional insert for the Rapid fFN Cassette for detailed intended use information.

GENERAL DESCRIPTION

The TLi$_{IQ}$® 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 provides one of three possible patient test results: Positive, Negative, or Invalid.

The result is positive if the signal intensity derived from the patient sample is greater than or equal to the reference calibration value specified by the calibration code. The result is negative if the signal intensity derived from the patient sample is less than the reference calibration value specified by the calibration code. 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.
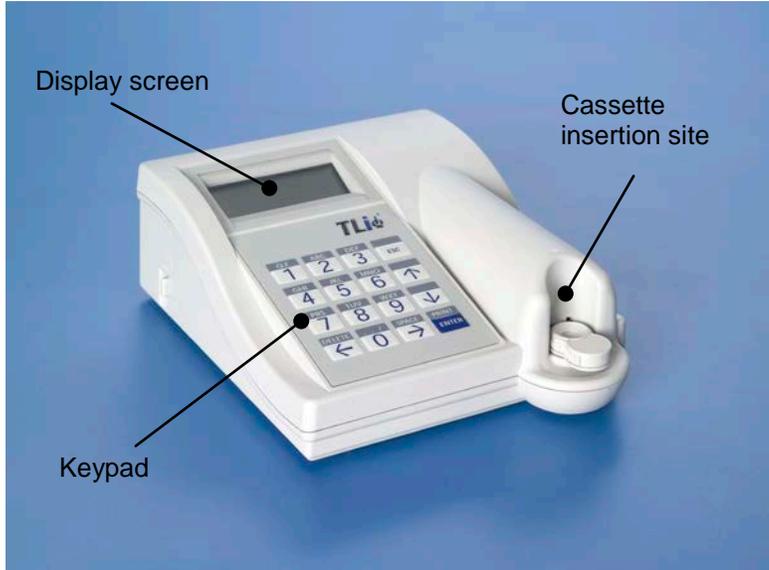
KEYPAD

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

Alpha – Use keypad to enter alpha characters from **A to Z.**
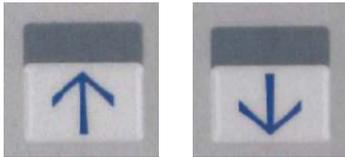
KEYPAD FUNCTIONS

(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).
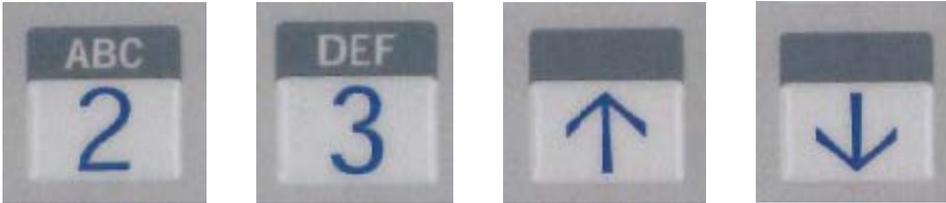
Example - to enter Cassette Lot Number **C9123**.

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.**
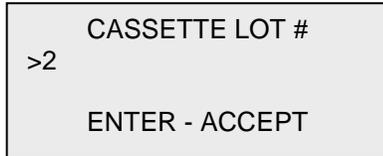
```
      CASSETTE LOT #
  >2


    ENTER - ACCEPT
```
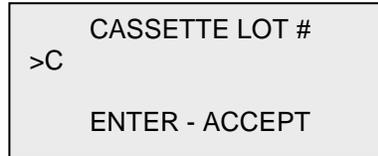
```
      CASSETTE LOT #
  >C


    ENTER - ACCEPT
```

2 - Press **9.**
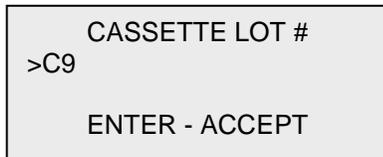
```
      CASSETTE LOT #
  >C9


    ENTER - ACCEPT
```

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

```
        CASSETTE LOT #
    >C912_


        ENTER - ACCEPT
```

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

```
        CASSETTE LOT #
    >C9123


        ENTER - ACCEPT
```

Example - to enter Patient Name **ABE**

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

```
        PATIENT ID

 >2


    ENTER - ACCEPT
```

```
        PATIENT ID

 >A


    ENTER - ACCEPT
```

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

```
        PATIENT ID

 >A2


    ENTER - ACCEPT
```

```
        PATIENT ID

 >AB


    ENTER - ACCEPT
```

3 - Press **3** to enter the next letter**.** Use ↑ or ↓ arrow until **E** appears on the display screen.
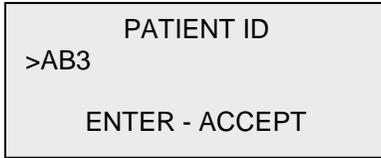
```
         PATIENT ID              
  >AB3                           


      ENTER - ACCEPT             
```
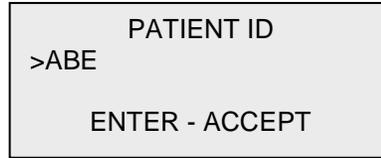
```
         PATIENT ID              
  >ABE                           


      ENTER - ACCEPT             
```

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

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 Cassette. This area of the instrument should be cleaned regularly (see Section 5).

DISPLAYED/PRINTED RESULTS

Each test result is displayed on the analyzer display screen. A test result requires three screens to display all of the data associated with the result. With AUTOPRINT ON, the test 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 DATA ACCESS mode.

Example: Displayed/Printed Results of Calibration Record

Displayed   Printed

```
   FETAL FIBRONECTIN
02:10 PM          10/26/07
SYSTEM CALIBRATED
USER:XXXXXXXXXXXX→
```

```
CAL CODE:FG56
CASSETTE LN:L1002
ANALYZER ID:01701
ESC-MAIN MENU        ←
```

```
      CYTYC® TLi™
-------------------------------
   RAPID fFN CALIBRATION
 SYSTEM CALIBRATED
 TIME:02:10p DATE:10/26/07
-------------------------------
 USER:JOHN SMITH
 CASSETTE LOT:L1002
 CALIBRATION CODE:FG56
 ANALYZER ID:01701
```

Example: Displayed/Printed Results of TLi$_{IQ}$ QCette®

Displayed   Printed

```
        QCette
 02:40 PM           10/26/07
 SYSTEM: PASS
 USER:XXXXXXXXXXXX  →
```

```
 CAL CODE:FG56
 QCette SN:004640
 ANALYZER ID:01701
 ESC-MAIN MENU      ←
```

```
     CYTYC® TLi™
  ----------------------
          TLi QCette
  TIME:02:40p DATE:10/26/07
  ----------------------
  SYSTEM: PASS
  ----------------------
  USER:JOHN SMITH
  SERIAL#:004640
  ANALYZER ID:01701
```

Example: Displayed/Printed Results of Negative Control Record

Displayed   Printed

```
   FETAL FIBRONECTIN
 02:45 PM          10/26/07
 NEG CTL:M1023
 RESULT:PASS           →
```

```
   INTERNAL CONTROLS
 USER:XXXXXXXXXXXXXX
 ANALYZER: PASS
 CASSETTE: PASS    ← →
```

```
 CAL CODE:FG56
 CASSETTE LN:L1002
 ANALYZER ID:01701
 ESC-MAIN MENU         ←
```

```
        CYTYC® TLi™
-----------------------------
 fFN NEGATIVE CTL RESULT
          PASS
 TIME:02:45p DATE:10/26/07
-----------------------------
 NEG CONTROL:M1023
 USER:JOHN SMITH
 CASSETTE LOT:L1002
 CALIBRATION CODE:FG56
 ANALYZER ID:01701
-----------------------------
     INTERNAL CONTROLS
 ANALYZER: PASS
 CASSETTE: PASS
```

Example: Displayed/Printed Results of Patient Record

Displayed   Printed

```
   FETAL FIBRONECTIN
03:02 PM          10/26/07
PT:XXXXXXXXXXXXXXXX
RESULT:POSITIVE        →
```

```
USER:XXXXXXXXXXXX
   INTERNAL CONTROLS
ANALYZER: PASS
CASSETTE: PASS    ← →
```

```
CAL CODE:BB11
CASSETTE LN:A2222
ANALYZER ID:01701
ESC-MAIN MENU        ←
```

```
      CYTYC® TLi™
      ------------------------
      RAPID fFN RESULT
         POSITIVE
   TIME:03:02p DATE:10/26/07
      ------------------------
   PATIENT:
   USER:JOHN SMITH
   CASSETTE LOT:A2222
   CALIBRATION CODE:BB11
   ANALYZER ID:01701
      ------------------------
      INTERNAL CONTROLS
   ANALYZER: PASS
   CASSETTE: PASS
```

Example: Displayed/Printed Results of Test Counts Record

Displayed   Printed

```
   FETAL FIBRONECTIN
TEST COUNTS
03:03 PM          10/26/07
ANALYZER:01701        →
```

```
PATIENT:4
CONTROL:1
QCette:1

                      ←
```

```
       CYTYC® TLi™

   FETAL FIBRONECTIN (fFN)
      TEST COUNT RECORD
  TIME:03:03p DATE:10/26/07
  ANALYZER ID:01701

  PATIENT:                4

  LIQUID CTL:             1

  QCette:                 1
```

SPECIFICATIONS

Power Supply	UL 12 VDC listed power supply
Memory Capacity	50 Calibration Records 50 QCette Records 50 Control Records 50 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 - 1.2 pounds
Operating Temperature	18° to 30°C
	64° to 86°F
A.C. Supply	120VAC / 60Hz / 16W or 220VAC / 50Hz / 16W
Input Connector	Coaxial power plug with positive center conductor
Output Connectors	9 pin male and 9 pin female data connectors

CAUTIONS AND WARNINGS

There are no known hazards associated with the TLi$_{IQ}$ 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 a grounded 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.

SECTION 2 – INSTALLATION

GENERAL
This section provides detailed installation instructions for the TLi$_{IQ}$ System. Follow installation steps carefully to insure proper installation and operation.

ENVIRONMENTAL FACTORS
The TLi$_{IQ}$ System has been designed to be safe under the following conditions: Indoor use; Altitudes up to 2000m; Maximum relative humidity of 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C; Main supply voltage fluctuations not to exceed ± 10% of the nominal; transient overvoltages according to Installation Category and Pollution Degree 2. However, as with all electronic instruments, prolonged exposure to high temperature and humidity should be avoided. The operating temperature should be held relatively constant. The optimum operating temperature is 18° to 30°C (64° to 86°F). Before operating, allow the instrument to equilibrate to room temperature.

Place the instrument where it will not be subjected to extreme temperature variations (e.g., near open windows, ovens, hot plates, radiators, direct sunlight).

UNPACKING

TLi$_{IQ}$ 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:

- TLi$_{IQ}$ Analyzer
- Power Adapter
- User Manual
- TLi$_{IQ}$ 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 (2 rolls)
- Power Cord
- Printer 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.

2. Connect the 9-pin connector of the printer cable to the analyzer and the modular jack to the printer.

System   Printer   Analyzer

3. Connect the small connector of the analyzer power adapter to the analyzer and the larger power connector to a grounded AC electrical outlet. **Caution:** Only power connectors provided with the TLi_{IQ} analyzer and printer may be used. Any substitutions can result in damage to the TLi_{IQ} analyzer and printer.

4. Connect the small connector of the printer power cord to the printer and the larger connector of the power cord to a grounded AC electrical outlet.

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 6, Troubleshooting.)

The analyzer will perform **SYSTEM DIAGNOSTICS** (a self-test of the analyzer components).

```
HOLOGIC TLi SYSTEM
    VERSION 2.0
SYSTEM DIAGNOSTICS
    IN PROCESS
```

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 TLi SYSTEM
    VERSION 2.0

03:00 PM        10/26/07
```

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

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.

```
        fFN MAIN MENU
4-ACCESS DATA
5-VIEW SETUP
6-CHANGE SETUP          ↑↓
```

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

```
        SETUP MENU
1-DATE/TIME
2-AUTOPRINT
3-INCUBATION MODE       ↓
```
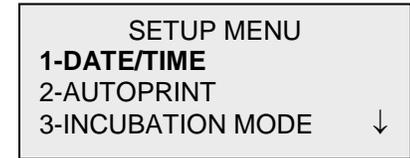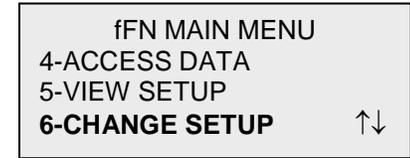
For more details about setting the date and time, see Section 4, Software Functions – Detailed Descriptions.

TLi_{IQ} QCette® SETUP

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.

```
        fFN MAIN MENU
4-ACCESS DATA
5-VIEW SETUP
6-CHANGE SETUP        ↑↓
```

2. From the SETUP MENU, press the ↓ or 4 to display QCette SETUP and follow the prompts.

```
        SETUP MENU
1-DATE/TIME
2-AUTOPRINT
3-INCUBATION MODE        ↓
```

```
        SETUP MENU
4-QCette SETUP


                         ↑
```
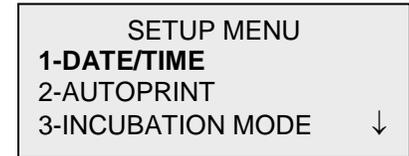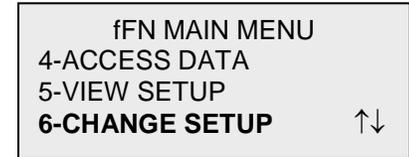
For more details about setting up the TLi_{IQ} QCette, see Section 4, Software Functions – Detailed Descriptions.

FACTORY DEFAULT SETTINGS

The TLi$_{IQ}$ 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.

INCUBATION MODE
Factory setting is INTERNAL Mode. The incubation mode refers to the timing of the incubation process and the initiation of the cassette analysis.

In the INTERNAL mode, the analyzer will time the incubation and automatically start the analysis when the incubation is complete.
In the EXTERNAL mode, the user will be responsible for timing the incubation and for starting the analysis.

NOTE: The INTERNAL mode is recommended by the manufacturer to ensure proper timing of the assay.

SECTION 3 – GENERAL OPERATING / TESTING INSTRUCTIONS

After instrument installation, the TLi$_{IQ}$ 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 on the analyzer using the on/off switch located on the left side of the analyzer.

The screen will display SYSTEM DIAGNOSTICS. If the analyzer fails the self-test, two beeps will sound; otherwise the analyzer will go to the next screen.

```
HOLOGIC TLi SYSTEM
VERSION 2.0
SYSTEM DIAGNOSTICS
IN PROCESS
```

Once SYSTEM DIAGNOSTICS is complete, the display will change to the software VERSION and the DATE and TIME for five seconds and then to the Main Menu. Verify the date and time are correct.
See Section 4 for setting Date/Time.

```
HOLOGIC TLi SYSTEM
VERSION 2.0

03:00 PM          10/26/07
```

2. Turn on the printer using switch at rear and ensure labels are in the printer. See Section 6 for loading printer labels.
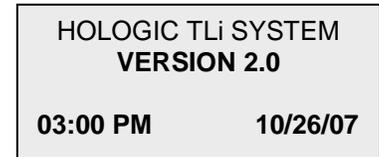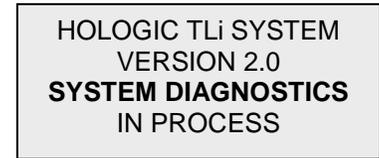
SET CALIBRATION

NOTE: Calibration must be set when changing cassette lots.

1. From the Main Menu, press 2 to select SET CALIBRATION.

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

2. Enter USER ID and press ENTER.

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

3. Enter the CASSETTE LOT# (on cassette pouch) and press ENTER.
   The lot number must be entered to proceed to the next step.

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

4. Enter the CALIBRATION CODE# (on cassette box label) and press ENTER. The code number must be entered to proceed to the next step.

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

```
SET CALIBRATION
CALIBRATION CODE#
>FG56
      ENTER-ACCEPT
```

5. When calibration is complete, the system will automatically display and print the result if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

```
FETAL FIBRONECTIN
03:00 PM          10/26/07
  SYSTEM CALIBRATED
USER:JOHN SMITH       →
```

6. Press ESC to return to the Main Menu.

TEST PATIENT (Internal Incubation Mode)

1. From the Main Menu, press 1 to select TEST PATIENT.

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

2. Enter USER ID and press ENTER.

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

3. Enter the **last two digits** of the CASSETTE LOT# (on cassette pouch) and press ENTER. The lot number must be entered to proceed to the next step.

NOTE: The analyzer will automatically compare the CASSETTE LOT# used to set calibration with the cassette lot number used for patient testing. If the lot numbers do not match, the analyzer will request the user to recalibrate the system. The cassette lot number used for calibration will be displayed on the third line.

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

4. Enter up to 16 alphanumeric characters for a PATIENT ID and press ENTER.

```
      PATIENT ID
>JANE DOE 123

    ENTER-ACCEPT
```

5. Insert cassette and press ENTER.

```
INTERNAL INCUBATION
   INSERT CASSETTE
     PRESS ENTER
    TO CONTINUE
```

6. Add sample and **immediately** press ENTER.

```
    ADD SAMPLE
  AND IMMEDIATELY
    PRESS ENTER
```

7. The analyzer will begin a 20-minute incubation countdown.

```
TEST IN PROCESS
DO NOT REMOVE
CASSETTE
19 MIN      56 SEC
```

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

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

9. When testing is complete, the system will automatically display and print the result if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

```
FETAL FIBRONECTIN
03:00 PM              10/26/07
PT:JANE DOE 123
RESULT:POSITIVE        →
```

10. Press ESC to return to the Main Menu.

DAILY QC

NOTE: TLi$_{IQ}$ QCette SETUP must be performed PRIOR to running the QCette as a quality control device. See Section 4 for TLi$_{IQ}$ QCette SETUP.

1. From the Main Menu, press 3 to select DAILY QC.

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

2. Enter USER ID and press ENTER.

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

3. Enter the QCette SN (on QCette plastic housing) and press ENTER. The serial number must be entered to proceed to the next step. The correct format is 6 numbers (e.g., 001004). Enter all leading zeros.

```
          QCette
      ENTER QCette SN
>001004
      ENTER-ACCEPT
```

NOTE: The serial number entered at daily QC must be identical to the serial number entered at TLi$_{IQ}$ QCette setup.

4.   Insert the QCette and press ENTER. The analyzer will begin the analysis of the QCette.

```
+------------------------+
|                        |
|     INSERT QCette      |
|                        |
|    ENTER-CONTINUE      |
|                        |
+------------------------+
```

```
+------------------------+
|    TEST IN PROCESS     |
|       ANALYZING        |
|    DO NOT REMOVE       |
|       CASSETTE         |
+------------------------+
```

5.   When testing is complete, the system will automatically display and print the result if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

6.   Press ESC to return to the Main Menu.

```
+------------------------+
|        QCette          |
| 03:00 PM       10/26/07|
| SYSTEM: PASS           |
| USER:JOHN SMITH     →  |
+------------------------+
```

LIQUID CONTROLS (Internal Incubation Mode)

1. From the Main Menu, press 8 to select LIQUID CONTROLS.

```
      fFN MAIN MENU
7-TEST COUNTS
8-LIQUID CONTROLS

                        ↓
```

2. Enter USER ID and press ENTER.

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

3. Enter the CASSETTE LOT# (on cassette pouch) and press ENTER. The lot number must be entered to proceed to the next step.

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

4. Select Negative or Positive Control.

```
 CONTROL TEST MENU
1-NEGATIVE CONTROL
2-POSITIVE CONTROL
```

5. Enter the CONTROL LOT# (on bottle label) and press ENTER.

```
  NEGATIVE CTL LOT#
>M1023

    ENTER-CONFIRM
```

6. Insert cassette and press ENTER.

```
INTERNAL INCUBATION
  INSERT CASSETTE
   PRESS ENTER
   TO CONTINUE
```

7. Add sample and **immediately** press ENTER.

```
ADD SAMPLE
AND IMMEDIATELY
PRESS ENTER
```

8. The analyzer will begin a 20-minute incubation countdown.

```
TEST IN PROCESS
DO NOT REMOVE
CASSETTE
19 MIN     56 SEC
```

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

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

10. When testing is complete, the system will automatically display and print the result if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

```
FETAL FIBRONECTIN
03:00 PM          10/26/07
NEG CTL:M1023
RESULT:PASS          →
```

11. Press ESC to return to the Main Menu.

VIEWING RESULTS ON SCREEN

Upon completion of every test, the analyzer will automatically display the results on up to three screens. Each screen can be accessed by using the ← and → keys. To print the result record, press the ENTER/PRINT key from any screen.

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 Cassette, (3) absence of conjugate aggregation, and (4) proper functioning of the TLi$_{IQ}$ analyzer hardware.

```
 FETAL FIBRONECTIN
03:00 PM          10/26/07
PT:JANE DOE 123
RESULT:POSITIVE       →
```

```
 INTERNAL CONTROLS
USER:JOHN SMITH
ANALYZER: PASS
CASSETTE: PASS     ← →
```

```
CAL CODE:FG56
CASSETTE LN:L1002
ANALYZER ID:00426
ESC-MAIN MENU        ←
```

INCUBATION MODE

The incubation mode may be Internal (incubation timed by analyzer) or External (incubation timed by user). The user prompts are the same for both modes until the analyzer reaches the "INSERT CASSETTE" screen.

NOTE: The INTERNAL mode is recommended by the manufacturer to ensure proper timing of the assay.

INTERNAL MODE – In this mode, pressing ENTER will prompt the user to add the sample and the analyzer will automatically complete the test. If the sample is not added within 2 minutes, the test is invalidated.


```
INTERNAL INCUBATION
  INSERT CASSETTE
   PRESS ENTER
   TO CONTINUE
```

```
   ADD SAMPLE
 AND IMMEDIATELY
  PRESS ENTER
```

```
 TEST IN PROCESS
  DO NOT REMOVE
    CASSETTE
19 MIN     56 SEC
```

EXTERNAL MODE – In this mode, the user is responsible for timing the incubation and starting the analysis. Upon completion of 20 minute incubation, insert cassette and press ENTER. The analyzer will automatically complete the test. If additional cassettes are run, wait at least 5 minutes before adding sample to the next cassette.
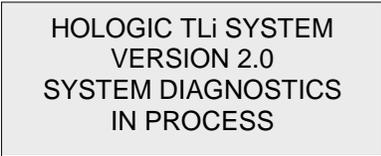
> EXTERNAL INCUBATION
> WHEN TIME COMPLETE
> INSERT CASSETTE
> AND PRESS ENTER

> TEST IN PROCESS
> **ANALYZING**
> DO NOT REMOVE
> CASSETTE

# SECTION 4 − SOFTWARE FUNCTIONS - DETAILED DESCRIPTIONS

STARTUP SCREEN

When the analyzer is turned on, the screen will display HOLOGIC TLi SYSTEM and the software version, while performing an internal self-test (SYSTEM DIAGNOSTICS).

```
HOLOGIC TLi SYSTEM
   VERSION 2.0
SYSTEM DIAGNOSTICS
   IN PROCESS
```
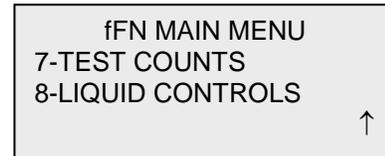
Following the self-test, the analyzer displays the software version and the current date and time for five seconds before displaying the Main Menu.
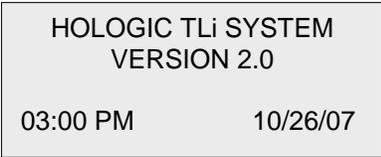
```
HOLOGIC TLi SYSTEM
   VERSION 2.0

03:00 PM        10/26/07
```

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, and Liquid Controls. Selecting the number in front of each option initiates that procedure or displays a submenu.

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

```
      fFN MAIN MENU
4-ACCESS DATA
5-VIEW SETUP
6-CHANGE SETUP         ↑↓
```

```
      fFN MAIN MENU
7-TEST COUNTS
8-LIQUID CONTROLS
                        ↑
```
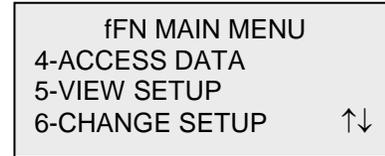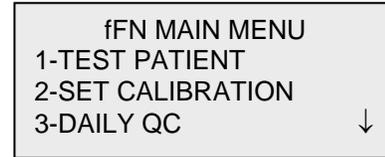
SET CALIBRATION
Option 2 on the Main Menu screen allows the user to set the calibration on the analyzer. Follow the analyzer prompts. Calibration must be set when changing cassette lots.

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.

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

The most recent USER ID is always displayed. Press ENTER to accept the ID, or enter a new User ID. This field will accept 15 alpha or numeric characters. To leave this field blank, delete the information using the ← key.

```
   SET CALIBRATION
       USER ID
>JOHN SMITH
     ENTER-CONFIRM
```
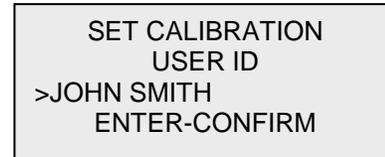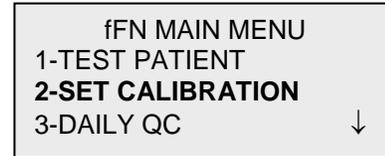
The CASSETTE LOT# must be entered to proceed to the next step. The CASSETTE LOT# is located on the cassette pouch. The software requires that the lot number is entered in the correct format: one alpha character followed by four numeric characters (e.g., L1002).

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

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: two alpha characters followed by two numeric characters (e.g., FG56).

```
   SET CALIBRATION
   CALIBRATION CODE#
>FG56
       ENTER-ACCEPT
```

NOTE: The calibration code is established by Hologic for each lot of Rapid fFN 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.

```
   FETAL FIBRONECTIN
03:00 PM          10/26/07
   SYSTEM CALIBRATED
USER:JOHN SMITH      →
```

```
CAL CODE:FG56
CASSETTE LN:L1002
ANALYZER ID:00426
ESC-MAIN MENU        ←
```

TEST PATIENT (Internal Incubation Mode)
Option 1 on the Main Menu screen allows the user to test a patient
sample. Follow the analyzer prompts.

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

The most recent USER ID is always displayed. Press ENTER to accept
the ID, or enter a new User ID. This field will accept 15 alpha or numeric
characters. To leave this field blank, delete the information using the ←
key.

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

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).

```
        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.

```
        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.

```
INTERNAL INCUBATION
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
```

A two-minute timer starts during which time this message flashes and the analyzer beeps. Add 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 20-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           │
│ 19 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.

```
┌─────────────────────────┐
│   ARE YOU SURE YOU      │
│ WANT TO CANCEL TEST     │
│   ENTER-CONTINUE        │
│   ESC-MAIN MENU         │
└─────────────────────────┘
```

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.

```
┌─────────────────────────┐
│ FETAL FIBRONECTIN       │
│ 03:00 PM      10/26/07  │
│ PT:JANE DOE 123         │
│ RESULT:POSITIVE      →  │
└─────────────────────────┘
```

Patient results are POSITIVE, NEGATIVE, or INVALID.

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

```
┌─────────────────────────┐
│   INTERNAL CONTROLS     │
│ USER:JOHN SMITH         │
│ ANALYZER: PASS          │
│ CASSETTE: PASS    ← →   │
└─────────────────────────┘
```

Invalid results will not be stored in memory.

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 Cassette, (3) absence of conjugate aggregation, and (4) proper functioning of the TLi$_{IQ}$ analyzer hardware.

```
┌─────────────────────────┐
│ CAL CODE:FG56           │
│ CASSETTE LN:L1002       │
│ ANALYZER ID:00426       │
│ ESC-MAIN MENU       ←   │
└─────────────────────────┘
```

DAILY QC

Prior to running the TLi$_{IQ}$ QCette® for the first time, QCette SETUP must be performed. See page 4-29. Refer to the TLi$_{IQ}$ QCette directional insert for more information.

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

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

The most recent USER ID is always displayed. Press ENTER to accept the ID, or enter a new User ID. This field will accept 15 alpha or numeric characters. To leave this field blank, delete the information using the ← key.

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

The QCette SN 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., 001004). Enter all leading zeros.

```
       QCette
    ENTER QCette SN
>001004
    ENTER-CONFIRM
```
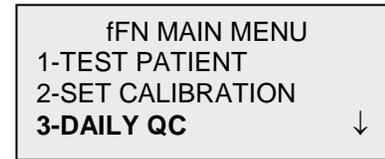
This message will be displayed if the QCette serial number entered is not identical to the serial number entered at the time of QCette setup.

```
CASSETTE # 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.

```
 CASSETTE NOT
   INSERTED

 ENTER-CONTINUE
```

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
```

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 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.

QCette results are SYSTEM PASS, SYSTEM FAIL, or INVALID.

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

Invalid results will not be stored in memory.

```
+---------------------------+
|          QCette           |
| 03:00 PM        10/26/07  |
| SYSTEM: PASS              |
| USER:JOHN SMITH       →   |
+---------------------------+
```

```
+---------------------------+
| CAL CODE:FG56             |
| QCette SN:00104           |
| ANALYZER ID:00426         |
| ESC-MAIN MENU         ←   |
+---------------------------+
```

LIQUID CONTROLS (Internal Incubation Mode)
Option 8 on the Main Menu screen allows the user to run the LIQUID CONTROLS.

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

The most recent USER ID is always displayed. Press ENTER to accept the ID, or enter a new User ID. This field will accept 15 alpha or numeric characters. To leave this field blank, delete the information using the ← key.

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

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).

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

The analyzer automatically compares the CASSETTE LOT# used to set calibration with the cassette lot number 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-NEGATIVE CONTROL or 2-POSITIVE CONTROL.

```
  CONTROL TEST MENU
1-NEGATIVE CONTROL
2-POSITIVE CONTROL
```

The most recent CONTROL LOT# is always displayed. Press ENTER to accept the lot number, or enter a new control lot number. This field will accept up to 12 alphanumeric characters.

```
  NEGATIVE CTL 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.

```
INTERNAL INCUBATION
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
```

A two-minute timer starts during which time this message flashes and the analyzer beeps. Add 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 20-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
19 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.

```
┌─────────────────────────────┐
│    ARE YOU SURE YOU         │
│  WANT TO CANCEL TEST        │
│     ENTER–CONTINUE          │
│     ESC–MAIN MENU           │
└─────────────────────────────┘
```

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 PASS, FAIL, or INVALID.

A FAIL or INVALID result should be repeated (See Section 7, Items 11 and 12.)

Invalid results will not be stored in memory.

```
┌─────────────────────────────┐
│   FETAL FIBRONECTIN         │
│ 03:00 PM          10/26/07  │
│ NEG CTL:M1023               │
│ RESULT:PASS            →    │
└─────────────────────────────┘
```

```
┌─────────────────────────────┐
│   INTERNAL CONTROLS         │
│ USER:JOHN SMITH             │
│ ANALYZER: PASS              │
│ CASSETTE: PASS      ← →     │
└─────────────────────────────┘
```

```
┌─────────────────────────────┐
│ CAL CODE:FG56               │
│ CASSETTE LN:L1002           │
│ ANALYZER ID:00426           │
│ ESC-MAIN MENU          ←    │
└─────────────────────────────┘
```

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

```
        fFN MAIN MENU
    4-ACCESS DATA
    5-VIEW SETUP
    6-CHANGE SETUP        ↑↓
```

Select option 1 on the ACCESS DATA MENU for VIEW/PRINT DATA.
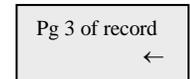
```
      ACCESS DATA MENU
    1-VIEW/PRINT DATA
    2-DATA TRANSFER
```
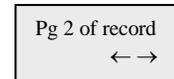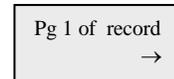
Select the category of data records to view/print. The categories are
displayed over two screens. Each screen can be accessed by using ↓
and ↑ keys.

```
      ACCESS DATA MENU
    1-PATIENT
    2-QCette
    3-CONTROLS              ↓
```

```
      ACCESS DATA MENU
    4-CALIBRATION

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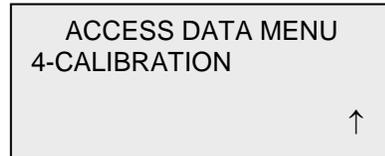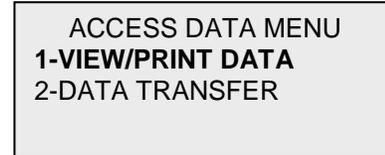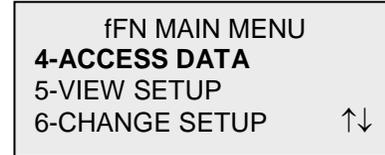
The most recent record for the category of data records selected will be displayed. PATIENT was chosen for this example. Use the $\uparrow$ and $\downarrow$ keys to view other records in the category.

Most Recent Patient Record N
$\downarrow$

Most Recent Patient Record N-1
$\uparrow\downarrow$

Earliest Patient Record
$\uparrow$
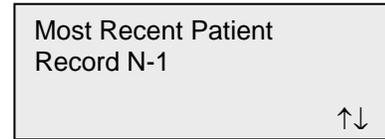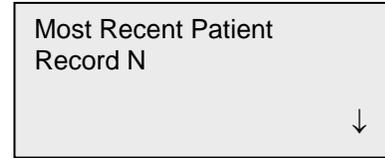
Use the $\leftarrow$ and $\rightarrow$ keys to view pages within a record.

Pg 1 of record	Pg 2 of record	Pg 3 of record
$\rightarrow$	$\leftarrow \rightarrow$	$\leftarrow$

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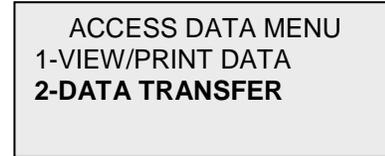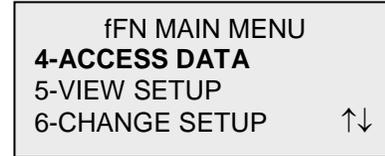
ACCESS DATA - DATA TRANSFER
Option 4 on the Main Menu screen allows the user to ACCESS DATA
for data transfer to a computer via an RS232 port.

```
      fFN MAIN MENU
 4-ACCESS DATA
 5-VIEW SETUP
 6-CHANGE SETUP        ↑↓
```

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

```
   ACCESS DATA MENU
 1-VIEW/PRINT DATA
 2-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 the laboratory 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
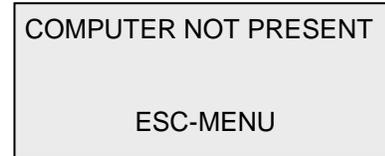once it has left the analyzer.

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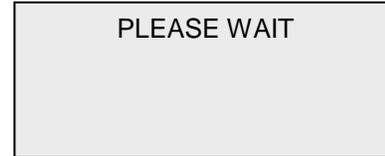
```
            PLEASE WAIT


```

This message will be displayed if a computer is not attached. Press ESC to return to the ACCESS DATA MENU.
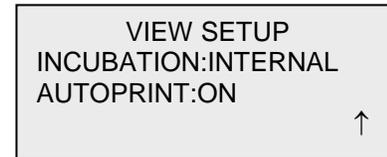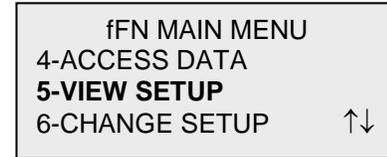
```
COMPUTER NOT PRESENT


      ESC-MENU
```

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

```
   fFN MAIN MENU
4-ACCESS DATA
5-VIEW SETUP
6-CHANGE SETUP      ↑↓
```

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

```
   VIEW SETUP
CAL CODE:FG56
DATE:10/26/07
TIME:03:00 PM        ↓
```

```
   VIEW SETUP
INCUBATION:INTERNAL
AUTOPRINT:ON
                     ↑
```

CHANGE SETUP – DATE/TIME

Option 6 on the Main Menu screen allows the user to change the DATE/TIME, Autoprint, or Incubation Mode, or to perform QCette Setup from the SETUP MENU.

```
     fFN MAIN MENU
4-ACCESS DATA
5-VIEW SETUP
6-CHANGE SETUP        ↑↓
```

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

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

```
      SETUP MENU
1-DATE/TIME
2-AUTOPRINT
3-INCUBATION MODE      ↓
```

```
      SETUP MENU
4- QCette SETUP


                       ↑
```
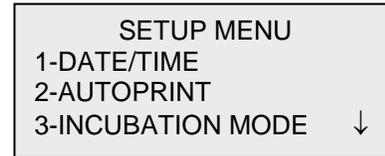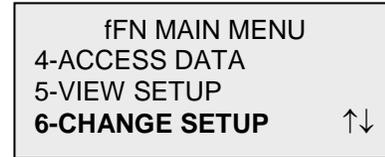
Enter the date at the cursor position on the SET DATE display.

```
      SET DATE
      MM/DD/YY
    >   /   /
    ENTER-ACCEPT
```

Single digit months and days must be preceded by a zero (e.g., September 9, 2007 will be entered as 09/09/07). Use the ← key to delete incorrect entries. Press ENTER to accept.

```
      SET DATE
      MM/DD/YY
     >09/09/07
    ENTER-ACCEPT
```

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

```
      SET TIME
    **1**-12 HOUR
    **2**-24 HOUR
```

12 Hour (AM/PM) Format
Enter the time at the cursor position on the TIME display.

```
         TIME
     _   :    AM
     ↑↓ AM/PM
     ENTER-ACCEPT
```

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.

```
         TIME
       09:09AM
     ↑↓ AM/PM
     ENTER-ACCEPT
```

24 Hour (Military Time) Format
Enter the time at the cursor position on the TIME display.

```
         TIME
       HH:MM
       >   :
     ENTER-ACCEPT
```

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.

```
         TIME
       HH:MM
       >09:09
     ENTER-ACCEPT
```
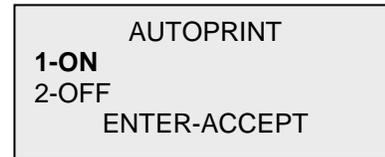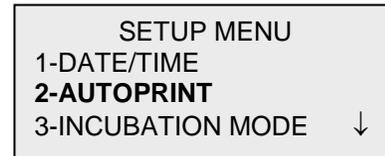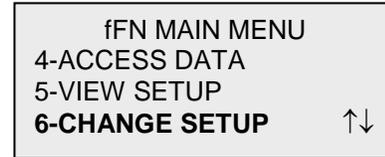
CHANGE SETUP – AUTOPRINT
Option 6 on the Main Menu screen allows the user to change the
Date/Time, AUTOPRINT, or Incubation Mode, or to perform QCette
Setup from the SETUP MENU.

```
      fFN MAIN MENU
4-ACCESS DATA
5-VIEW SETUP
6-CHANGE SETUP        ↑↓
```

Select option 2 on the SETUP MENU to change AUTOPRINT.

```
      SETUP MENU
1-DATE/TIME
2-AUTOPRINT
3-INCUBATION MODE      ↓
```

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.

```
      AUTOPRINT
1-ON
2-OFF
      ENTER-ACCEPT
```

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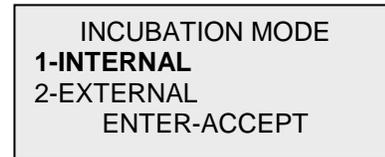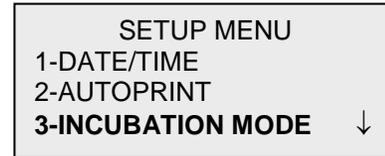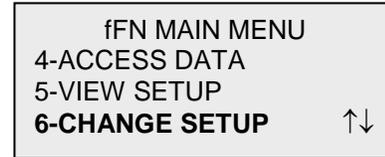to accept and return to the SETUP MENU.

CHANGE SETUP – INCUBATION MODE

Option 6 on the Main Menu screen allows the user to change the Date/Time, Autoprint, or INCUBATION MODE, or to perform QCette Setup from the SETUP MENU.

```
      fFN MAIN MENU
4-ACCESS DATA
5-VIEW SETUP
6-CHANGE SETUP        ↑↓
```

Select option 3 on the SETUP MENU to change INCUBATION MODE.

```
      SETUP MENU
1-DATE/TIME
2-AUTOPRINT
3-INCUBATION MODE      ↓
```

In the Internal Mode, the analyzer times the incubation and starts the analysis. External Mode requires the user to manually time the incubation and start the analysis.

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

```
    INCUBATION MODE
1-INTERNAL
2-EXTERNAL
      ENTER-ACCEPT
```

CHANGE SETUP – TLi$_{IQ}$ QCette® SETUP

Option 6 on the Main Menu screen allows the user to change the Date/Time, Autoprint, or Incubation Mode, or to perform QCette SETUP from the SETUP MENU.

```
     fFN MAIN MENU
4-ACCESS DATA
5-VIEW SETUP
6-CHANGE SETUP       ↑↓
```

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

```
     SETUP MENU
1-DATE/TIME
2-AUTOPRINT
3-INCUBATION MODE     ↓
```

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 4 on the SETUP MENU to begin QCette SETUP.
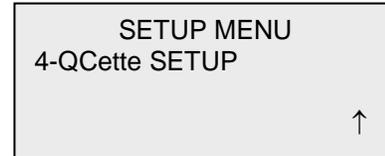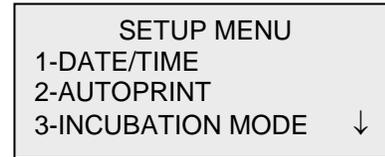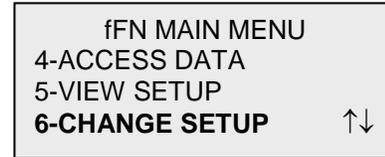
```
     SETUP MENU
4-QCette SETUP


                      ↑
```

The most recent USER ID is always displayed. Press ENTER to accept the ID, or enter a new User ID. This field will accept 15 alpha or numeric characters. To leave this field blank, delete the information using the ← key.

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

The QCette SN 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., 001004). Enter all leading zeros.

```
       QCette SETUP
      ENTER QCette SN
>001004
       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 willl 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 12-15 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 completion of the QCette Setup, this message will be displayed. SETUP COMPLETE indicates that the performance criteria of the analyzer have been established.
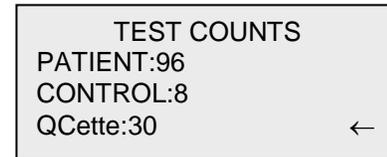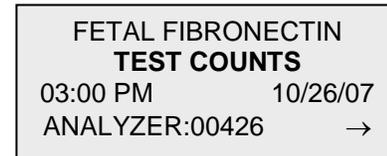
```
QCette
SETUP COMPLETE

ESC-MAIN MENU
```

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. Please refer to Section 7, Troubleshooting.

```
QCette
SETUP ERROR
NNNN
ESC-MAIN MENU
```

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).

```
  fFN MAIN MENU
7-TEST COUNTS
8-LIQUID CONTROLS
                        ↑
```

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

```
 FETAL FIBRONECTIN
    TEST COUNTS
03:00 PM        10/26/07
 ANALYZER:00426     →
```

```
    TEST COUNTS
PATIENT:96
CONTROL:8
QCette:30           ←
```

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
- 75% Isopropyl Alcohol
- BacDown® (disinfectant)

SECTION 6 – PRINTER

LOADING PRINTER LABELS

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. The adjustable spool design holds labels of any width.

4.   Remove the RIGHT SIDE of the spool by sliding it off the right end.

5.   Remove the tape from the end of a new roll of labels. Cut the lead label in half to create a clean straight edge. The printer feeds a straight edge much easier than a rough edge.

Figure 1

6.   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). The labels will feed from the bottom of the roll.

a

7.   Ensure the power cord is connected. Turn on the printer (On/Off switch is located at the back of the printer). The green power light will flash and the printer motor will run as it looks for labels to feed.

b
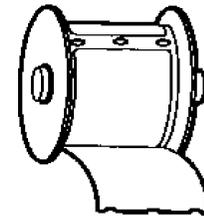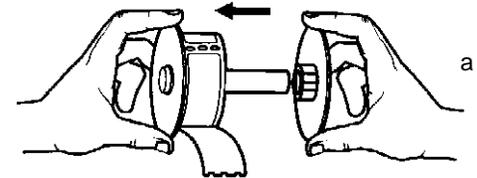
8.   Holding the spool of labels in one hand, use the other hand to feed the free end of the roll into the feed slot on the inside of the printer, as shown in Figure 2. (If it is easier, rest the labels on the top edge of the printer, freeing both hands to feed the labels.)

Figure 2

9.   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.)

10.   Insert the label spool into the printer. The spool will fit into the raised shoulder slots in the printer.

11.   Close the cover and the printer is ready to print labels.
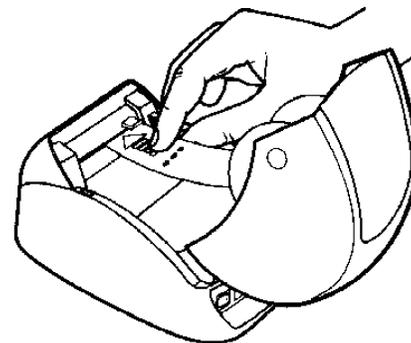
REMOVING AN EMPTY LABEL ROLL

When the printer is out of labels, the green 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

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.

SECTION 7 – TROUBLESHOOTING

GENERAL INFORMATION

The TLi$_{IQ}$ 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 Service for any questions related to the performance of your TLi$_{IQ}$ System.

ITEM	PROBLEM	SOURCE	SOLUTION
1	Analyzer display screen is blank.	Analyzer Power Cord and Adapter	Ensure analyzer power cord is firmly connected to analyzer. Ensure analyzer power adapter is plugged into a grounded AC electrical outlet.
		ON/OFF Switch	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	Analysis process is interrupted and/or unusual characters appear on display screen, and the analyzer does not respond to keypad inputs.	Electrostatic Discharge	Turn analyzer off and back on to reinitialize the system. Proceed with testing.
4	Printer fails to print.	Printer Power Cord	Ensure printer power cord is firmly connected to printer. Ensure printer power cord is plugged into a grounded AC electrical outlet.
		ON/OFF Button	Ensure green light is lit. This indicates printer is on.
		Printer Cable	Ensure printer cable is connected to the printer and the analyzer.
		Printer Labels	Ensure printer is not out of printer labels. To order printer labels, contact Hologic Inc.

ITEM	PROBLEM	SOURCE	SOLUTION
5	Printer not on when test was run.	Printer	Turn printer on. Recall the test result on the analyzer display screen. Press PRINT/ENTER on the analyzer to print the result.
6	Printer output in unusual font.	Printer	Turn analyzer and printer off and back on.
7	Analyzer turned off after calibration, or power failure occurred after calibration.	Power	The calibration remains in memory. Reset calibration only if prompted by analyzer.
8	Cassette cannot be removed.	Analyzer	Turn analyzer off and back on to reinitialize the system.

ITEM	PROBLEM	SOURCE	SOLUTION
9	TLi$_{IQ}$ QCette failed to complete setup.	TLi$_{IQ}$ QCette	Ensure QCette is clean and not damaged. Repeat TLi$_{IQ}$ QCette setup as described in Section 4. If the QCette setup fails a second time, call technical service.
		Analyzer	Turn analyzer off and back on to reinitialize the system. Repeat TLi$_{IQ}$ QCette setup as described in Section 4. If the QCette setup fails a second time, call technical service.
10	TLi$_{IQ}$ QCette failed during daily quality control.	TLi$_{IQ}$ QCette	Ensure QCette is clean and not damaged. Repeat TLi$_{IQ}$ QCette daily quality control as described in Section 4. If the QCette testing fails a second time, call technical service.
		Analyzer	Turn analyzer off and back on to reinitialize the system. Repeat TLi$_{IQ}$ QCette daily quality control as described in Section 4. If the QCette testing fails a second time, call technical service.

ITEM	PROBLEM	SOURCE	SOLUTION
11	Liquid control failed.	Liquid Control	Review the control procedures and repeat the test.

Verify the control has not expired, and is neither cloudy nor discolored.

If the control fails a second time, call technical service. |
| 12 | Invalid liquid control test result. | Analyzer Internal Controls: Analyzer Fail/Cassette Pass | Refer to Error/Invalid Code table.

Run TLi$_{IQ}$ QCette to verify analyzer is functioning properly.

Do not bump or jar analyzer during the test. |
| | | Analyzer Internal Controls: Analyzer Pass/Cassette Fail | Review the Rapid fFN Cassette Kit directional insert to ensure the correct procedure was followed.

Examine the cassette. Cassette imperfection may cause an invalid test result. Rerun control on a fresh cassette. |

ITEM	PROBLEM	SOURCE	SOLUTION
13	Invalid patient test result.	Analyzer Internal Controls: Analyzer Fail/Cassette Pass	Refer to Error/Invalid Code table. Run TLi$_{IQ}$ QCette to verify analyzer is functioning. Do not bump or jar analyzer during the test.
		Analyzer Internal Controls: Analyzer Pass/Cassette Fail	Review the Rapid fFN Cassette Kit directional insert to ensure the correct procedure was followed. Examine the cassette. Viscous patient samples that flow slowly may require testing by an alternate format such as the fFN Enzyme Immunoassay. Examine the cassette. Cassette imperfection may cause an invalid test result. Rerun patient sample on a fresh cassette.
14	Computer not present message appears.	Data Transfer	Refer to Section 4, pp. 21, 22.

ERROR/INVALID CODES

ERROR CODE	DEFINITION	TROUBLE SHOOTING PROCEDURE
720, 721	Possible Motor Problem	Turn analyzer off and back on to reinitialize the system. If error code persists, call technical service.
621, 622	Possible Optics Problem	Turn analyzer off and back on to reinitialize the system. If error code persists, call technical service.
Other Codes		Call technical service

SECTION 8 – SERVICE AND WARRANTY

TECHNICAL SERVICE

Analyzer
The TLi$_{IQ}$ 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 Technical Service.

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

CONTACT INFORMATION

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

TECHNICAL SERVICE (USA/Canada)

Tel: 1-888-PRETERM (1-888-773-8376)
                         1-800-442-9892
Fax: 1-508-263-2967

TECHNICAL SERVICE (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:	0041.21.633.39.26
Italy:	800 786 308		

Intl Fax number: 0041.21.633.39.10

Replacement Parts

Item	Catalog Number
Analyzer Power Adapter	00989
Printer Power Cord	01206
Printer Serial Cable	01087
Printer Labels	01088
TLi$_{IQ}$ QCette$^®$	01175
User Manual	01207

Contact fFN Customer Service to order replacement parts.

CONTACT INFORMATION

fFN CUSTOMER SERVICE (USA/Canada)

Tel:	1-888-PRETERM (1-888-773-8376)
	1-800-442-9892
Fax:	1-508-229-2860

fFN CUSTOMER SERVICE (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:	0041.21.633.39.26
Italy:	800 786 308		

Fax: Intl Fax number: 0041.21.633.39.10

TLi$_{IQ}$® 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 Service Department of Hologic Inc. by calling 1-888-PRETERM (1-888-773-8376) or 1-800-442-9892 for assistance and/or instructions for obtaining repair of the system.