Click on item below:

ABBOTT LCx PROBE SYSTEM

Abbott LCx® Thermal Cycler Operations Manual

List Number 8B28-01

Manufactured for Abbott Laboratories
Abbott Park, IL 60064
47287-102 –June 1996

Foreword

The Abbott LCx Thermal Cycler is an accessory of the Abbott LCx Probe System. The LCx Thermal Cycler is backed by dedicated professionals with expertise in engineering, training and technical information.

As a valued customer, Abbott will teach you how to operate, maintain and troubleshoot the LCx Probe System and its accessories when you attend our PACE accredited training program at our Dallas, Texas facility.

It is extremely important that you operate and maintain the thermal cycler safely.

To this end, customer support is offered in several forms:

- This manual is designed to serve as a reference to operation of the thermal cycler. Please examine it carefully and become familiar with its contents.
- Technical assistance is available. This gives you access to our specially trained staff of Abbott Customer Support Specialists.

Customer Support Center (CSC)

Abbott Laboratories Diagnostics Division

United States: 1-800-527-1869

Canada English: 1-800-387-8378
Canada French: 1-800-456-2675

Other Countries: Call your local Customer Service Representative

Intended Use

The Abbott LCx Thermal Cycler is intended for use only with the Abbott LCx Probe System.

Proprietary Statement

The manual has been developed solely for use with Abbott Laboratories equipment, for *in vitro* diagnostic applications as specified in the operating instructions. All operating instructions must be followed.

Pictorial Disclaimer

The sample screens contained in this manual are for information and illustration purposes only. This information is not to be used for clinical or maintenance evaluation.

Inquiries

Please direct all inquiries concerning information in this manual to Abbott Laboratories at the following address:

Probe Diagnostic Business Unit
Abbott Diagnostics Division
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064

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List of Safety Icons

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	**WARNING:** Electrical Shock Hazard	7-3
Refer to **Section 7:** ***Operational Precautions and Limitations*** and **Section 8:** ***Hazards*** for more details on the specific precautions and hazards.		

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How to Use This Manual

Overview

This Operations Manual contains complete instructions for using and maintaining the LCx Thermal Cycler. The manual is designed to provide step-by-step instructions for thermal cycler users. You will find it a valuable aid and essential reference source.

This section of the manual provides an overview of the information presented in the manual, including:

- Manual organization
- Manual construction
- Text conventions
- Special messages

The material in this section is designed to assist the user in finding information about the setup, operation, maintenance, and troubleshooting of the LCx Thermal Cycler.

For specific information regarding a section, refer to the Master Table of Contents.

Manual Organization

This manual is organized to guide you through every step necessary for the proper operation of the LCx Thermal Cycler.

Topics are organized into sections. Each section begins with a brief overview followed by general information about the subject.

Section 1: *Use or Function*

This section describes the capabilities, features, and functions of the LCx Thermal Cycler.

Section 2: *Installation Procedures and Special Requirements*

This section describes how to set up your LCx Thermal Cycler for operation. It includes information about site preparation and thermal cycler requirements.

Section 3: *Principles of Operation*

Refer to this section for a better understanding of the technology used by the Abbott LCx Probe System and the LCx Thermal Cycler.

Section 4: *Performance Characteristics and Specifications*

Performance characteristics, physical specifications, and environmental requirements of the thermal cycler are presented in this section.

Section 5: *Operating Instructions*

Use this section to learn how to perform the various tasks related to programming and running thermal amplifications.

Section 6: *Calibration Procedures*

Here you will find information on calibration of the LCx Thermal Cycler.

Section 7: *Operational Precautions and Limitations*

This section presents factors that might adversely affect the quality of instrument output.

Section 8: *Hazards*

This section discusses possible physical hazards an operator may encounter while using the LCx Thermal Cycler.

Section 9: *Service and Maintenance*

This section provides information on the care and upkeep of the LCx Thermal Cycler.

Section 10: *Troubleshooting and Diagnostics*

Refer to this section for probable causes and corrective actions whenever a problem is observed.

Bibliography

This is a listing of reference sources for the user who wishes more background information about the LCx Probe System or the LCx Thermal Cycler.

Revision Status and Log

The Revision Status and Log provide a history of manual revisions and the methods of updating the manual.

Glossary

The Glossary contains information on the technical terms and acronyms used throughout the LCx Thermal Cycler Operations Manual.

Index

The Index provides an alphabetically compiled list of pertinent topics and their location within the manual.

Manual Construction

The *Abbott LCx Thermal Cycler Operations Manual* is divided into sections. By referring to the Master Table of Contents, the Index, or a table of contents in a particular section, you can easily find specific information.

Master Table of Contents

Lists each section of the manual.

Section Separators

A separator tab marks the start of each section. Immediately following each tab is a section table of contents.

Index

The Index provides the location of specific topics or items of information.

Text Conventions

Procedural instructions are explained using numbered steps.

Illustrations appear where they are useful to the explanation. Display illustrations help you ensure that you have accessed the correct display or completed an action properly.

References to sections and subsections are presented in bold and italic fonts, for example: **Section 9:** ***Service and Maintenance,*** **Subsection:** ***Daily Maintenance***.

Names of function keys appear in bold typeface between brackets and typically are preceded by an action word, such as:

Pressd **[FILE]**
[4]
[ENTER]

Instrument parameters that must be entered by the user are presented in bold typeface. Numeric values are represented by the number to be entered and are always entered with the numeric keypad.

An instrument display or prompt is pictured as a single ruled frame.

```
STEP-CYCLE FILE
STEP to edit file #4
```

Instrument Keys may be graphically displayed in this manner:

Certain common words are assigned precise meanings in the manual. For example, here are three words defined in **Section 5:** ***Operating Instructions,*** **Subsection:** ***Overview:***

- PRESS – used to indicate that the described action can only be performed on the operator control panel.
- SELECT – used to indicate that one of the described action options must be chosen to proceed.
- ENTER – used to indicate that the described action is to be performed or that the selected data is to be registered into a data field.

With usage, these words quickly assume their specific meanings.

Special Messages

Throughout the text, icons and signal words appear where the nature of the information warrants special attention.

NOTE: This message is used to indicate important information.

WARNING: Potential Biohazard. The *biohazard* icon labels an activity or area where the operator may be exposed to infectious materials or substances.

WARNING: Electrical Shock Hazard. The *electrical* warning icon alerts the operator to the possibility of electric shock in the described activity or at the posted location. When located on the analyzer, this icon refers the operator to the manual for information about the hazard.

WARNING: The *general* warning icon identifies a physical, mechanical, or procedural situation where the user must be aware, alert, and cautious to prevent injury, instrument failure or erroneous results.

CAUTION: This message is used to indicate a potentially serious condition if instructions are not followed.

Be alert to the special meanings of these icons.

Use or Function
Section Table of Contents

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Overview

In this section, you will find:

- A basic overview of the LCx Probe System
- A detailed description of the LCx Thermal Cycler including the following subsystems and user interfaces:
  - Sample Block
  - Keypad
  - Files
  - Displays

NOTES

LCx Probe System

The LCx Probe System integrates three distinct processes:

- **Specimen Preparation** releases the nucleic acid from its native biological source.
- **Nucleic Acid Amplification** exponentially generates copies of the specific nucleic acid sequence of interest.
- Automated **Amplified Nucleic Acid Detection** utilizes an immunoassay technique to detect the nucleic acid amplification products.

Refer to **Section 3:** ***Principles of Operation***, for technical details about the LCx Probe System.

NOTES

Product Description

LCx Thermal Cycler

The LCx Thermal Cycler is a temperature cycling instrument designed specifically to automate nucleic acid amplification.

The LCx Thermal Cycler contains a programmable heating and cooling block that can hold up to 48 LCx amplification vials. The instrument performs repeated temperature cycling profiles on samples contained in amplification vials.

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Subsystems

The LCx Thermal Cycler consists of the following subsystems and components:

- Sample block
- Sample block cover
- Control panel (indicator lights, display, keypad)
- Power switch
- Fuse
- Power cord connection

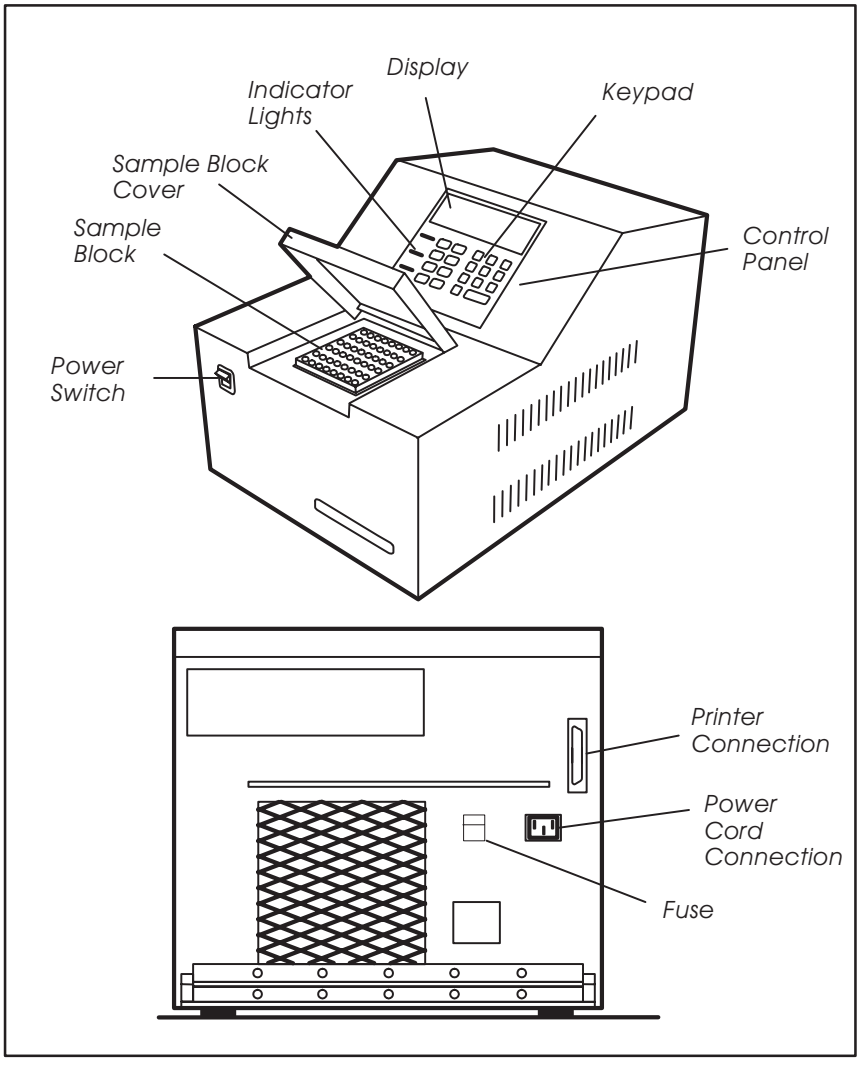

Figure 1.1: Components of the LCx Thermal Cycler
(120V instrument shown).

Sample Block

The aluminum sample block has 48 positions and can be programmed for heating and cooling.

Sample Block Cover

The sample block cover is used to maintain temperature uniformity.

Control Panel

The instrument control panel consists of:

- Keypad
- 40-Character fluorescent display
- 3 Indicator lights

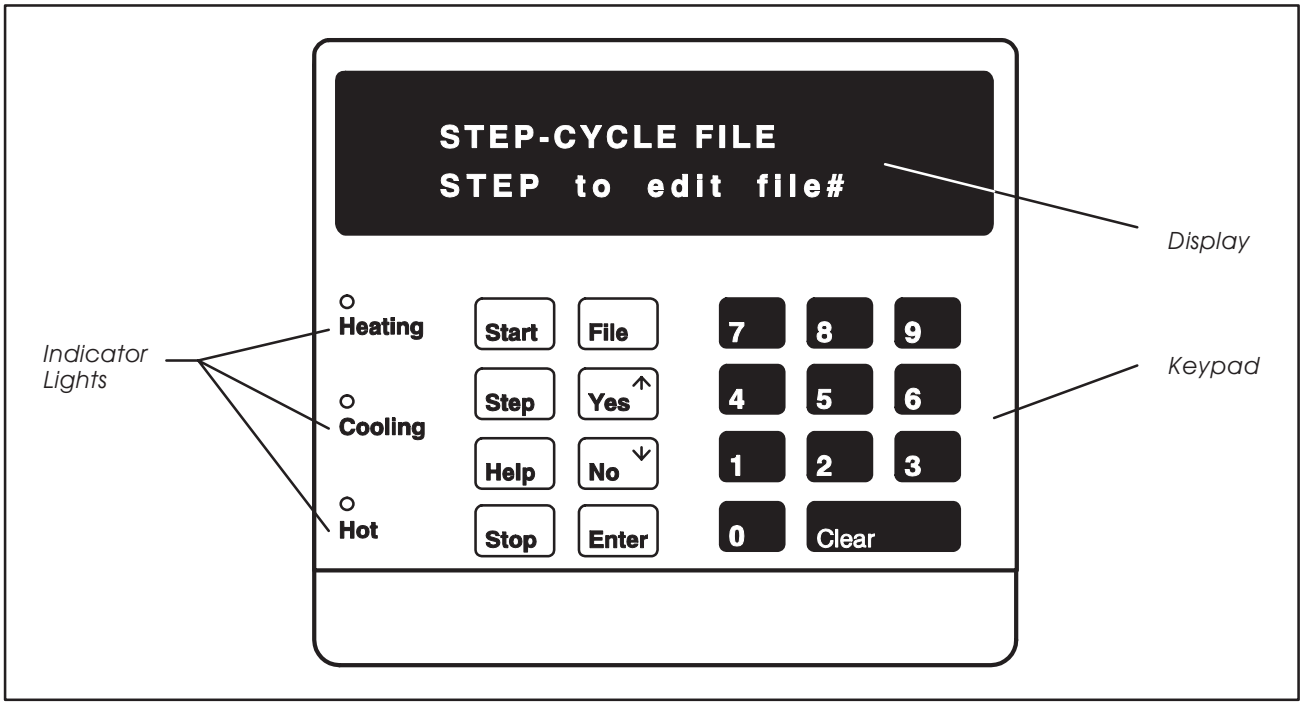

Figure 1.2: Control Panel

Keypad

The keypad is a standard ten number keypad with nine function keys used to create, edit, store, view, or run files.

START

The **Start** key begins a run from the first display in a file.

STEP

The **Step** key enables you to:

- view the next display in a file
- accept a default value and move to the next parameter when editing a file

HELP

The **Help** key enables you to:

- view the previous display in a file
- move to the previous parameter when editing a file
- toggle between the two run-time displays when running samples

STOP

While editing a file, press the **Stop** key:

- ONCE to move to the last display in a file
- TWICE to move to the first display in that file

While performing other functions, press the **Stop** key:

- ONCE to pause a run in progress
- TWICE to abort a Soak file run
- THREE TIMES to abort a Time Delay, Thermo-Cycle, or Step-Cycle file run in progress

CAUTION: If the thermal cycler run is interrupted or aborted, the run is invalid. Do not continue to process these samples. Make sure the amplification vial caps are tightly closed. Remove carefully to a biohazard bag. Seal the bag and dispose of according to waste disposal procedures in **Section 8:** ***Hazards,*** **Subsection:** ***Biosafety.***

FILE

Use the **File** key in combination with:

- a numeric key and the **Enter** key to access a file
- the **Enter** key to access the File Directory
- the **Yes** key to access the Configuration and Diagnostic functions
- the **Clear** key to delete a file whose first display currently appears on the screen

YES

The **Yes** key:

- stores a newly created file
- completes the deletion of a file initiated by the **File** and **Clear** key sequence
- overwrites a file number that was used previously

NO

The **No** key enables you to:

- move the cursor from one selection to the next on a display
- enter negative values from –5° to –1°C, for example, to enter a temperature of –5°C, press **No**, then **5**, then **Enter**

ENTER

The **Enter** key enables you to:

- accept a displayed value and move to the next parameter
- accept a selection, e.g., RUN, and initiate that operation

CLEAR

The **Clear** key clears the current value from the display.

- The **Clear** key used in combination with the **File** key deletes the file whose first display currently appears.

Numeric Keys

Numeric Keys are used to enter values for amplification parameters and for file and user numbers.

Display

The display is a 40-character, blue fluorescent screen (20 characters × 2 lines). During a run the display is updated continuously with the current temperature of the sample block and current elapsed time. Temperature of the sample block is displayed in degrees Celsius.

Indicator Lights

The LCx Thermal Cycler has three lights that indicate when the sample block is heating, cooling, or hot. The "hot" light illuminates when the temperature of the sample block is greater than 50°C.

⚠ **WARNING:** To protect yourself against burns, do not open the sample block cover or touch the sample block when the **HOT** light is illuminated. This indicates a block temperature above 50°C. Do not open the sample block cover until a sample block temperature of less than 37°C is displayed.

⚠ **CAUTION:** If the thermal cycler run is interrupted or aborted, the run is invalid. Do not continue to process these samples. Make sure the amplification vial caps are tightly closed. Remove carefully to a biohazard bag. Seal the bag and dispose of according to waste disposal procedures in **Section 8:** ***Hazards,*** **Subsection:** ***Biosafety.***

NOTES

Components

Electrical

Fuses

There is one user-accessible fuse on the LCx Thermal Cycler. It is a slow-blow fuse. Its amperage rating depends on the voltage of the instrument. See **Section 2:** ***Installation Procedures and Special Requirements,*** **Subsection:** ***Electrical Requirements.***

Power Cord

The power cord is a three-prong grounded cord. The power cord is specific to the voltage of the instrument.

Ancillary Components

Amplification Vials

The amplification vials supplied with the assay contain all the reagents necessary for nucleic acid amplification. Addition of sample to the vial followed by thermal cycling of that mixture is all that is required for the amplification process. Refer to the assay-specific package insert for details on specimen preparation and nucleic acid amplification.

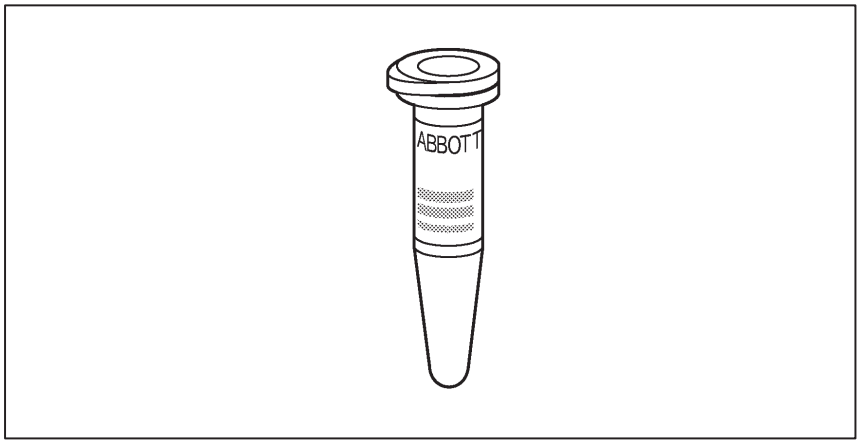

Figure 1.3: LCx Amplification Vial

NOTES

System Files

Instructions to the LCx Thermal Cycler are stored in system files. A file is a set of instructions. It is used to specify how the instrument should heat and cool samples in either a thermal cycle or a fixed temperature incubation. Each file appears as a series of displays. These displays show the time and temperature parameters that are needed to run the amplification.

The LCx Thermal Cycler system software allows you to:

- Access one of the four built-in default files
- Create, store, edit and review files
- Link several files together
- Access the File Directory to review your amplification files
- View the current status of a thermal cycle on one of two run-time displays
- Access the Configuration and Diagnostic Files to delete files and test the heating and cooling functions

There are four default files stored in the LCx Thermal Cycler. The thermal cycler is programmed by editing parameters and by linking files as described in the assay-specific package insert.

Default Files

The four default files (Files 1 through 4) stored permanently in the instrument software are:

- Cycle/Amplification files
  - Step-Cycle Files (File #4)

    The Step-Cycle file contains a series of thermal plateaus or "hold" times. These plateaus are referred to as segments. Thermal transitions in a Step-Cycle file cannot be programmed but are achieved as quickly as possible.
  - Thermo-Cycle Files (File #3)

    The Thermo-Cycle file contains up to 16 temperature and time *segments*.
- Incubation files
  - Time Delay Files (File #2)

    A Time Delay file allows you to set and maintain the temperature of the sample block at a specific level.
  - Soak Files (File #1)

    Target "hold" temperatures are edited in the Soak file. The target temperature in the Soak File is achieved as soon as possible and held until the run is aborted.

Section 2

Installation Procedures and Special Requirements

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Overview

This section describes how to install the LCx Thermal Cycler and supplies electrical and environmental requirements for this accessory.

In this section, you will learn how to perform the following installation procedures:

- Unpack the LCx Thermal Cycler
- Verify your accessory package components
- Install and initialize your LCx Thermal Cycler

In addition, you will:

- Verify proper installation by performing pre-operational system tests

If you experience any difficulties with the installation of your LCx Thermal Cycler, contact the LCx CSC.

NOTES

Site Preparation

Physical Characteristics

Size	20.5″ D × 13″ W × 12″ H (52.1 cm D × 33 cm W × 30.5 cm H)
Weight	65 lbs (29.5 Kg)

Electrical Requirements

Voltage	120, 220/230/240, or 100 VAC
Frequency	60 Hz, 50 Hz or 50/60 Hz
Power	9 Amps, 5 Amps, 11 Amps
Fuse (F1)	120 VAC – 10 Amp, slow-blow, 3AG, 250V 220/230/240 VAC – 6.3 Amp T, (5 × 20 mm), 250V 100 VAC – 12 Amp, slow-blow, 3AG, 250V
Installation Category	Able to withstand transient overvoltage according to Installation Category II as defined in IEC 1010-1

Environmental Requirements

Room Temperature	15° – 30°C (59° – 86°F)
Relative Humidity	20 – 80% (without condensation)
Altitude	0 – 6,562 Ft. (2000 meters)
Ventilation	6 inch (15 cm) minimum space on each side, top, and back. **Do not place next to a heat generating device.**
Location	Flat, level surface. No direct sunlight or drafts. Remove from sources of direct heat and moisture. Pollution Degree 2. (Normal office environment)
Heat Output	LCx Thermal Cycler Idle 1650 BTU/hr. Cycling 2400 BTU/hr.

NOTES

Unpacking

Carefully remove your LCx Thermal Cycler from the shipping carton.

⚠ **WARNING:** Do not attempt to lift or move the thermal cycler without assistance. Improper lifting can cause painful and sometimes permanent back injury. Use proper lifting techniques when lifting or moving the thermal cycler.

Inspect it for signs of damage. If there has been any damage in transit, contact LCx CSC to report the damage.

Keep the shipping carton and all packing material intact.

Be sure the following items have been shipped with your LCx Thermal Cycler.

Description	Quantity	Part/List Number
❑ LCx Thermal Cycler System Operations Manual (English)	1	8B28-01
❑ Fuses (10 Amp, 6.3 Amp, or 11 Amp)	1	—
❑ Power Cord (100V or 120V)	1	—

NOTE: For instruments set at 230V, use a cord set consisting of a minimum 0.75 mm cord and grounding type attachment plug rated 10A, 250V. The cord set should have the appropriate safety approvals for the country in which the equipment will be installed and should be marked HAR (harmonized).

❑ Temperature Verification System	1	2C40-01

Contact LCx CSC if any of these items are missing.

NOTES

Setup Procedures

Electrical

The LCx Thermal Cycler operates on a 120, 220/230/240 or 100 VAC power source. Connect the LCx Thermal Cycler to a dedicated electrical source using a three-prong, grounded outlet without an extension cord.

⚠ **WARNING:** Before you turn the instrument on for the first time at installation, be sure that the instrument has been upright for at least four hours at normal indoor temperatures (15°C to 30°C).

NOTES

Pre-Operational System Tests

The Cooling and Heater tests are used to check the performance of the cooling and heating systems. Both tests must be run during installation.

Cooling Test

The cooling test verifies the efficiency of the cooling system. Turn the thermal cycler on and let it warm up for at least 15 minutes.

Table 2.1: Cooling Test Procedure

Display	Keystrokes	Task
The first display of any file	**FILE**, **1**, **ENTER**	Access the default Soak File
`SOAK FILE` `STEP to edit file #1`	**STEP**	View temperature parameter of Soak File
`Soak Temperature` `(–5 to 100) 25°C`	**4**, **ENTER**	Change temperature to 4°C
`End of file` `RUN-STORE-PRINT`	**ENTER**	Select Run option
`SOAK FILE` `START to run file# 1`	**START**	Run edited Soak File & verify sample block temperature
`SOAK=4°C Blk=XX°C` `E.T.=XX:XX FILE #1`		Record sample block temperature @ 15 minutes*
	STOP	Exit Cooling Test
`ABORT FILE?` `Press STOP or START`	**STOP**	Abort run

***If the displayed temperature is not 4°C ±1°C, contact LCx CSC.**

Heater Test

The Heater Test measures the maximum heating rate and the heating time in seconds that are required for the first 15 degrees of temperature change. The system then displays this information.

Table 2.2: Heater Test Procedure

Display	Keystrokes	Task
The first display of any file	**FILE**, **YES**	Access Configuration and Diagnostic option
`Select Function` `CONFIG-DIAGNOSTIC`	**NO**, **ENTER**	Select Diagnostics
`Diagnostic Tests` `Enter test # (1-6)`	**3**, **ENTER**	Run Heater Test
`Heater Test Blk= xxC` `going to 35C...`		Sample block going to 35°C
`Heater Test Blk= 35C` `wait 1 min... :xx`		Sample block temperature reaches 35°C and holds for 1 minute
`Heater Test Blk= xxC` `heating...`		Sample block temperature warming

Heating Rate ↓
`Heat Rate= X.XX°/sec`
`Time= XXs`
↑ *Heating Time*
		Sample block temperature displays

`Heat Rate= X.XX°/sec` `Time= XXs`	**STOP**	Exit Heater Test
`Diagnostic Tests` `Enter test # (1-6)`	Test Number, **ENTER** or **STOP**	Run another Diagnostic Test or Exit Diagnostic File

Compare your results with Table 2.3. If any of the numbers displayed at the end of the test are outside the normal range, contact LCx CSC.

Table 2.3: Heater Test Results by Line Voltage

			Your heater rate should be ≥:	Your heating time should be ≤:
100 VAC	240 VAC	120 VAC	0.67 °/second	30 seconds

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Principles of Operation
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Overview

This section provides information on the three distinct processes used when performing LCx assays. These are:

- Specimen preparation
- Nucleic acid amplification
- Detection of amplification product

There is also a description of the four file types used in the LCx Thermal Cycler and how each affects the nucleic acid amplification process.

NOTES

Nucleic Acid Amplification Technology

The LCx Thermal Cycler is an accessory of the LCx Probe System. This integrated system is designed to detect specific nucleic acid sequences in human specimens using amplified nucleic acid probe technology.

The LCx Probe System integrates three distinct processes:

1. **Specimen Preparation** releases the nucleic acid from its native biological source.
2. **Nucleic Acid Amplification** exponentially generates copies of the specific nucleic acid sequence of interest.
3. Amplified **Nucleic Acid Detection** utilizes MEIA technology to detect the nucleic acid amplification products.

The process flow is shown in Figure 3.1.

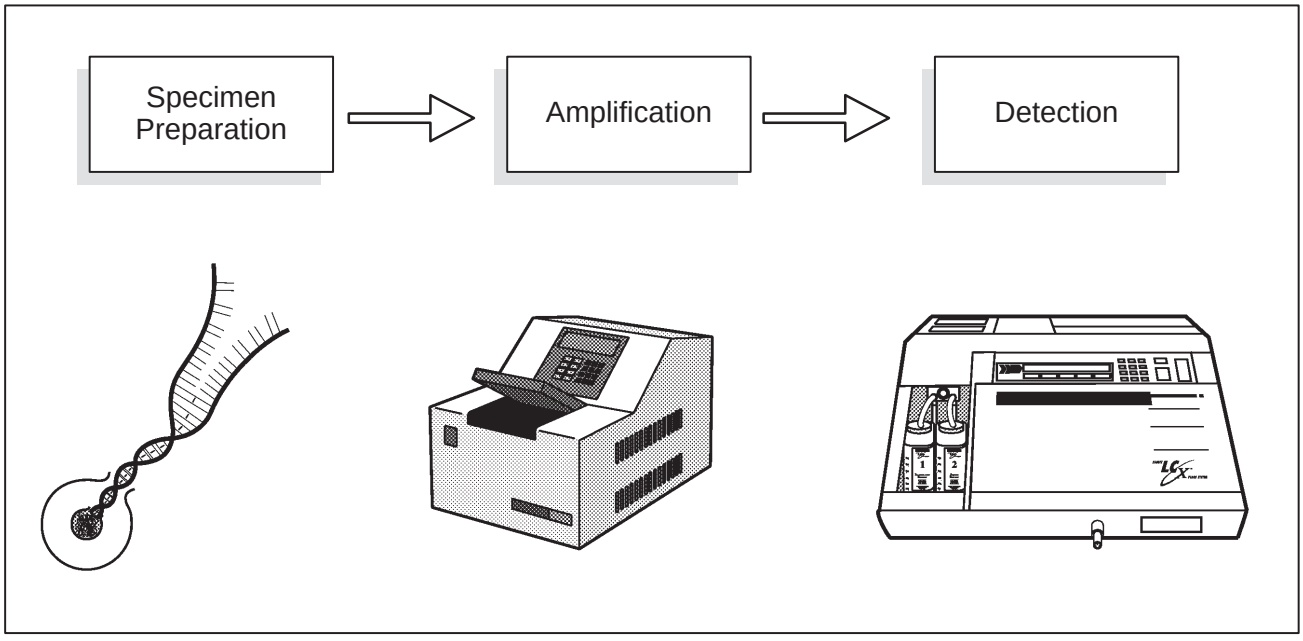

Figure 3.1: Process Flow

Specimen Preparation

The LCx Probe System is designed for direct detection of nucleic acid target sequences. Specimen preparation releases the nucleic acid target from its native biological source such as a bacterial cell, and makes the target available for amplification.

To release the nucleic acid target, a thermal pretreatment is required.

Specimen preparation steps and required accessories are described in each assay-specific package insert.

Nucleic Acid Amplification

The LCx Probe System uses the Ligase Chain Reaction (LCR) for nucleic acid amplification. This process is performed in the LCx Thermal Cycler.

If the specimen being analyzed contains the target nucleic acid sequence of interest, two oligonucleotide probes bind to each strand of the target sequence. Two enzymes, polymerase and ligase, acting sequentially, join probes that have hybridized at adjacent positions on a given strand of target DNA, creating copies of the target. Thus, in one cycle, the amount of the target nucleic acid doubles. The copies plus the original target will function as templates for the joining of additional probes in subsequent cycles. The number of target nucleic acid copies doubles during each cycle of the amplification process. After 30 to 40 thermal cycles, the target sequence can theoretically be copied up to a billion-fold.

The LCx Thermal Cycler is programmed by the operator using the parameters given in the assay-specific package insert. All reagents needed for the amplification process are contained in the amplification vial. A volume of the processed sample is added to the contents of the amplification vials and is then thermally cycled. An explanation of each step of the LCR reaction follows.

1. Heating to Denature

   The sample in the amplification vial is heated by the thermal cycler to denature the double-stranded target nucleic acid and the probes.

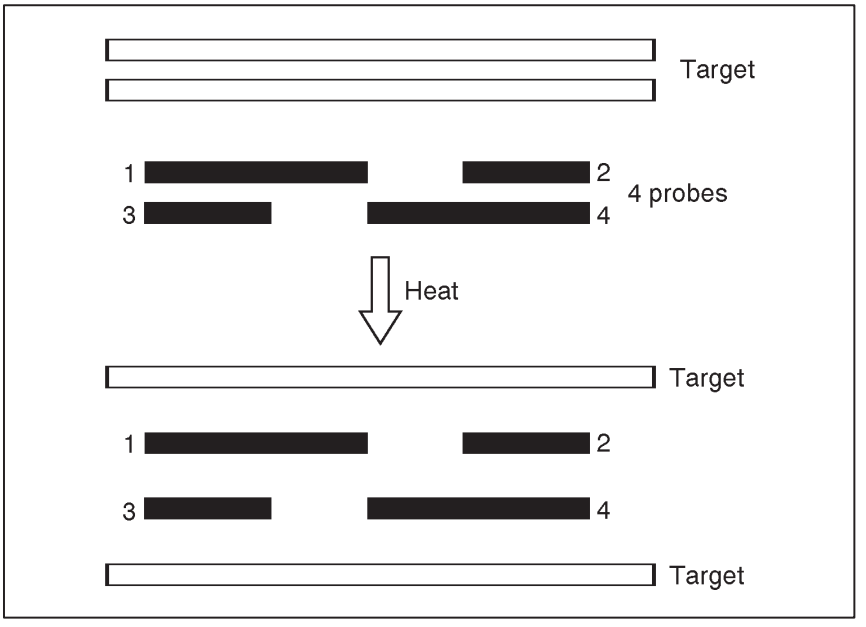

Figure 3.2: **Step 1** *Heating to Denature*

2. Cooling to Anneal

   The thermal cycler temperature is lowered. The probes are in great excess compared to the target nucleic acid, and hybridize to complementary single-stranded target sequences. Two probes hybridize to each strand of target leaving a gap between them ranging in length from one to several bases depending on the assay.

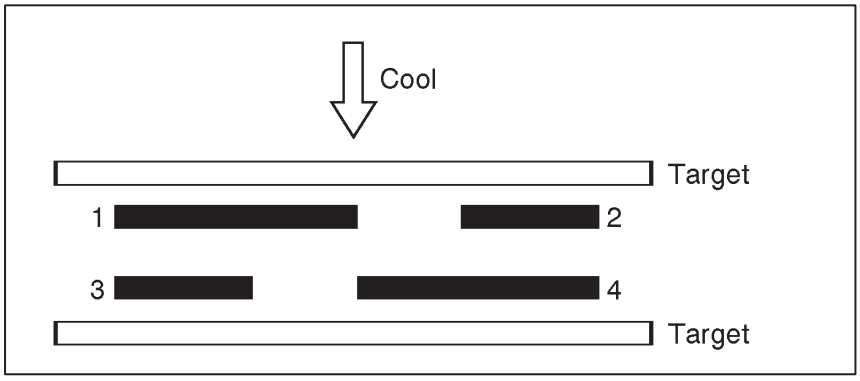

Figure 3.3: **Step 2** *Cooling to Anneal*

3. Gap Filling

   The gap between the probes is filled using a thermostable polymerase and a subset of deoxyribonucleotide triphosphates (dNTPs).

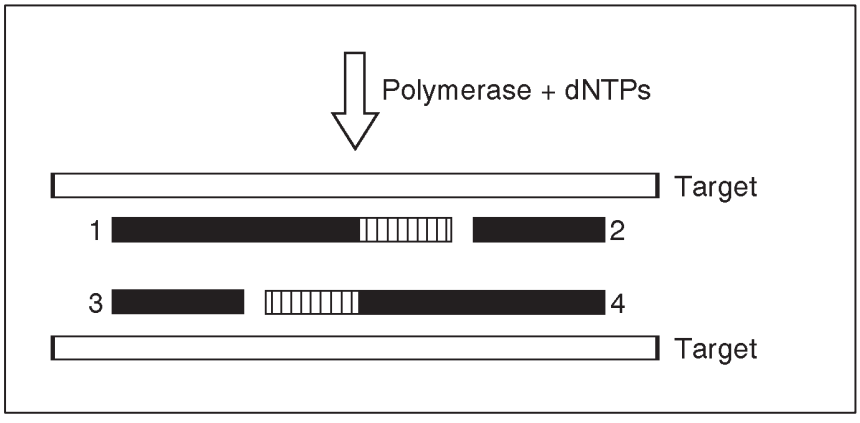

Figure 3.4: **Step 3** *Gap Filling*

4. Ligation

   The probes are now adjacent and can be joined, or ligated, using a thermostable ligase. As a result of the ligation, the number of copies of the target sequence doubles. Steps 1 through 4 are then repeated, ideally doubling the number of targets each time. The Ligase Chain Reaction amplification product is subsequently detected.

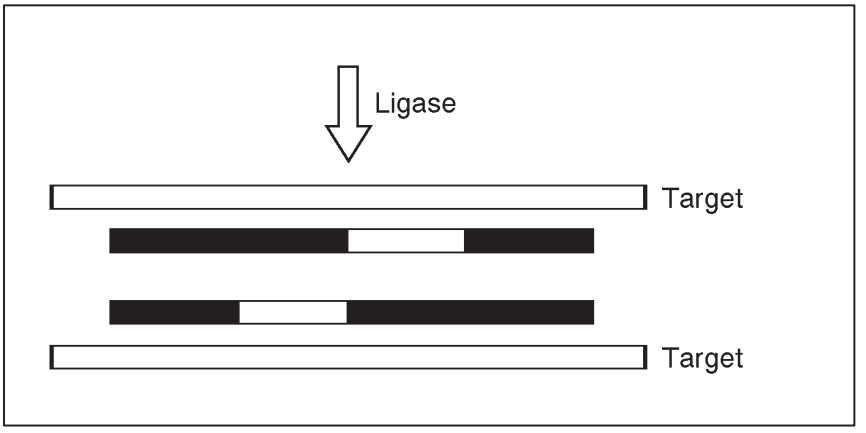

Figure 3.5: **Step 4** *Ligation*

Nucleic Acid Detection

During amplification, the number of copies of the target nucleic acid sequence is increased several orders of magnitude. Finally, the LCx Analyzer uses Microparticle Enzyme Immunoassay (MEIA) for detecting amplification product.

Microparticle Enzyme Immunoassay (MEIA) technology uses submicron-sized microparticles coated with antibodies that "capture" the analyte being measured. The effectively large surface area of microparticles and the small diffusion distance between the analyte and solid phase result in increased assay kinetics and decreased assay incubation times. The microparticles, along with the bound analyte, are separated from the reaction mixture by binding irreversibly to the glass fiber matrix used in the LCx Reaction Cell.

NOTES

File Descriptions

The LCx Thermal Cycler has several files. Each file contains temperature and time segments. The operator will edit these files using parameters in the assay-specific package insert. A description of each file follows.

Step-Cycle File

A Step-Cycle file (File #4) is an amplification file that contains one or more temperature and time segments. You may think of a Step-Cycle file as a series of hold times. The hold time is the period of time that the target temperature will be maintained. Thermal transitions are achieved as quickly as possible. The hold time clock starts 1°C before the target temperature is achieved.

There are usually three active segments and one terminating segment in a Step-Cycle file. The Step-Cycle file can have up to 99 cycles.

The active segments include:

1. Denature
2. Anneal (where hybridization starts)
3. Gap filling and ligation (where hybridization continues)

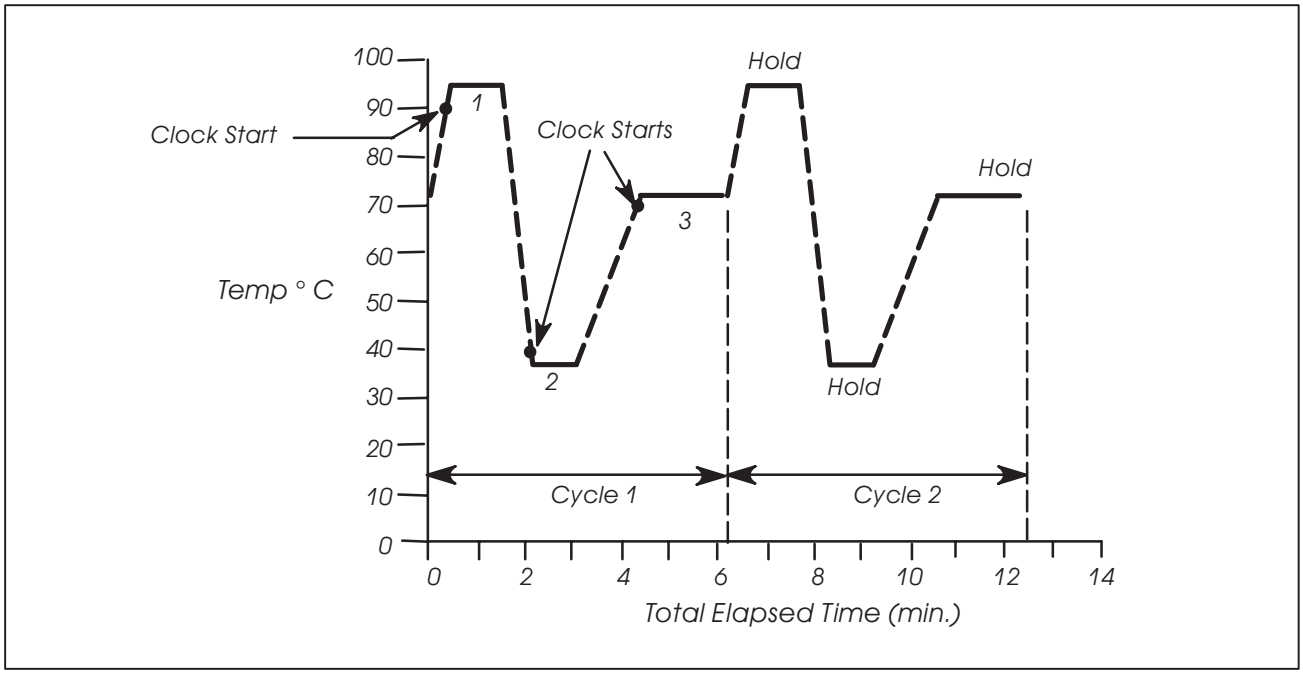

Figure 3.6: Diagram of a Step-Cycle file.

Soak File

A Soak file (File #1) is an incubation file in which the target temperature is achieved as soon as possible and held indefinitely until the run has been aborted. Soak files are often used after thermal cycling when you want to protect your amplified samples against degradation, especially on overnight runs.

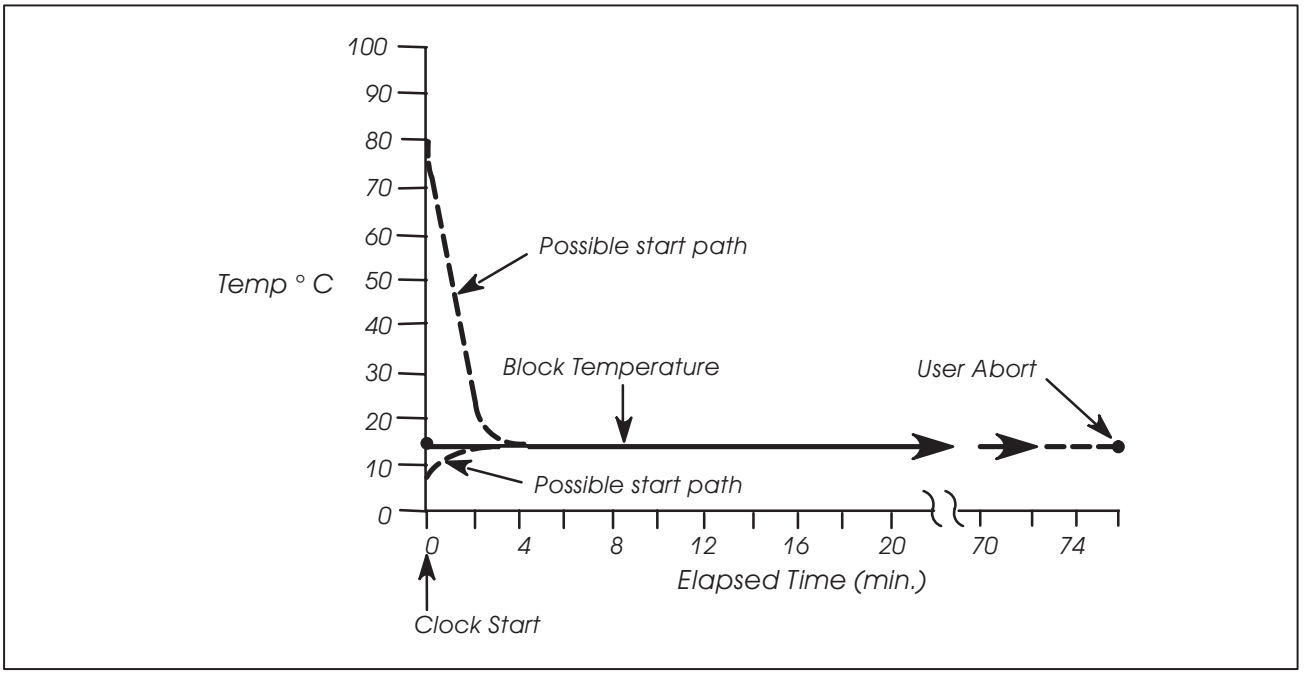

Figure 3.7: Diagram of a Soak file.

Thermo-Cycle File

A Thermo-Cycle file (File #3) is an amplification file that contains one or more temperature and time *segments*. Segments are either odd-numbered or even-numbered.

Odd-numbered segments contain a target temperature and a *ramp time*. The ramp time is the length of the thermal transition. The default ramp time for each odd-numbered segment is one second. Ramping is not instantaneous. The one second default value indicates that the sample block will reach the target temperature as quickly as possible.

Even-numbered segments contain a target temperature and a *hold time*. The hold time clock starts 1°C before the target temperature is achieved.

A Thermo-Cycle file has six segments:

1. Temperature Ramp Up
2. Denature
3. Temperature Ramp Down
4. Anneal
5. Temperature Ramp Up
6. Gap-filling and Ligation

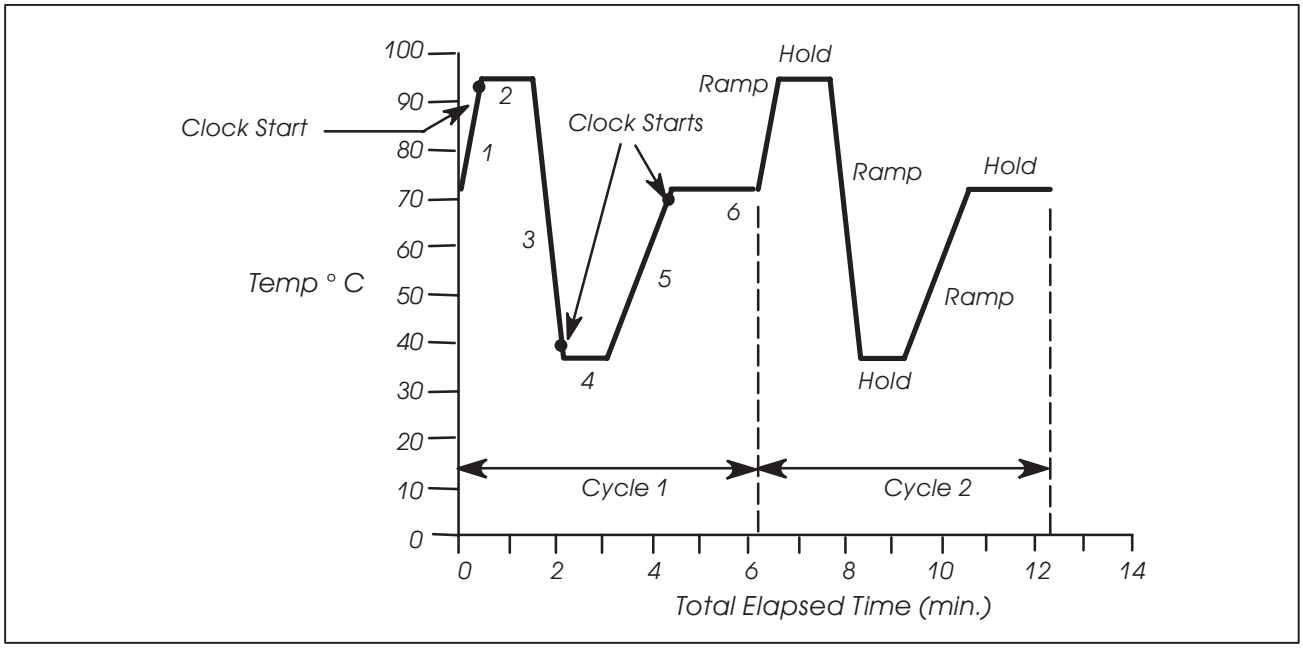

Figure 3.8: Diagram of a Thermo-Cycle file.

Time Delay File

Time Delay files (File #2) are often used as high-temperature incubation files to destroy unwanted proteases and nucleases present in the DNA sample before thermal cycling.

In a Time Delay file the temperature of the sample block is set and maintained at a specific level. The *delay time* is the length of time that the sample block is under thermal control. The delay time includes both the transition time and incubation time. For example, a delay time of seven minutes may include 50 seconds of transition time and 6:10 minutes of incubation (see Figure 3.9).

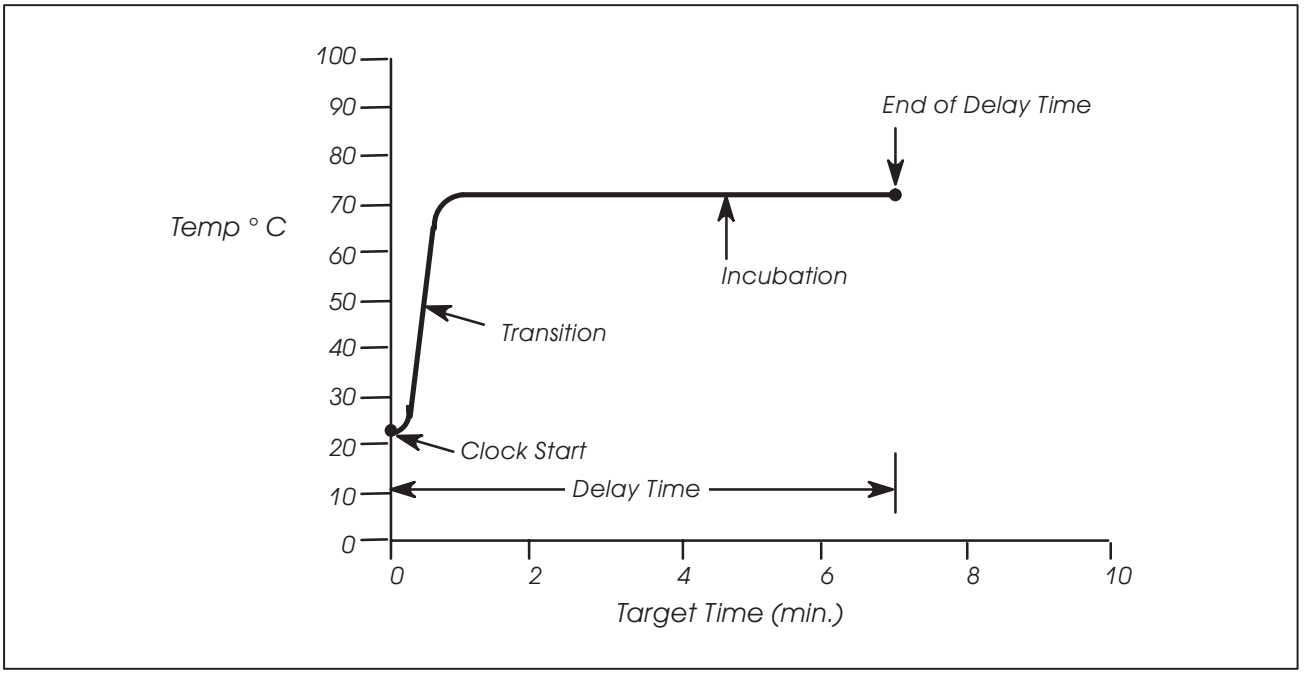

Figure 3.9: Diagram of a Time Delay file.

Section 4

Performance Characteristics & Specifications

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NOTES

Overview

This section describes the physical characteristics and specifications of the LCx Thermal Cycler. It covers what the LCx Thermal Cycler can do and what is required to run the thermal cycler properly.

In this section, you will find the system specifications for:

- Physical Characteristics
- General Characteristics
- Environmental Requirements
- Electrical Characteristics
- Temperature
- Ramp Time and Rate
- System Features

NOTES

Specifications

Physical Characteristics

Size

20.5″ D × 13″ W × 12″ H (52.1 cm D × 33 cm W × 30.5 cm H)

Weight

65 lbs (29.5 Kg)

General Characteristics

Sample Block

The covered sample compartment contains an aluminum block with 48 amplification vial positions in a 6 x 8 format.

Display

The LCx Thermal Cycler uses a 40 character blue fluorescent display (20 characters x 2 lines). The temperature of the sample block is displayed in degrees Celsius. The resolution of the temperature display is 1°C.

Environmental Requirements

Room Temperature	15° – 30°C (59° – 86°F)
Relative Humidity	20 – 80% (without condensation)
Altitude	0 – 6,562 Ft. (2000 meters)
Ventilation	6 inch (15 cm) minimum space on each side, top, and back. **Do not place next to a heat generating device.**
Location	Flat, level surface. No direct sunlight or drafts. Remove from sources of direct heat and moisture. Pollution Degree 2. (Normal office environment)
Heat Output	LCx Thermal Cycler Idle 1650 BTU/hr. Cycling 2400 BTU/hr.

Electrical Characteristics

Power

The LCx Thermal Cycler operates on one of three power selections. The power requirements of these instrument versions are:

- 120 VAC, 60 Hz, 9 Amps
- 220/230/240 VAC, 50 Hz, 5 Amps
- 100 VAC, 50/60 Hz, 11 Amps

Fuses

- one fuse, labeled F1. The following table shows which fuses are used in each instrument version.

Table 4.1: Fuse Requirements

Instrument Version	F1
120 VAC	10 Amp, slow-blow, 3AG, 250V
220/230/240 VAC	6.3 Amp T (5 × 20 mm), 250V
100 VAC	12 Amp, slow-blow, 3AG, 250V

Installation Category

This instrument is able to withstand transient overvoltage according to Installation Category II as defined in IEC 1010-1.

Temperature

Block Temperature Range

- -5° to 100°C.

  NOTE: -5°C can only be achieved in laboratories with ambient temperatures less than 25°C and humidity less than 85%.

Block Temperature Accuracy

- accurate to:
  - within 3°C for programmed temperatures less than 32°C
  - within 1°C for programmed temperatures between 33°C and 100°C.

Static Block Temperature Uniformity

- ±0.5°C after 90 seconds from clock start, over a range of 35°C to 100°C, and
- ±2°C after 90 seconds from clock start, for temperatures less than 35°C.

Dynamic Block Temperature Uniformity

- Less than ±1°C when the clock starts, for temperatures between 35°C and 100°C.

Figure 4.1 illustrates static and dynamic block temperature uniformity during an up ramp.

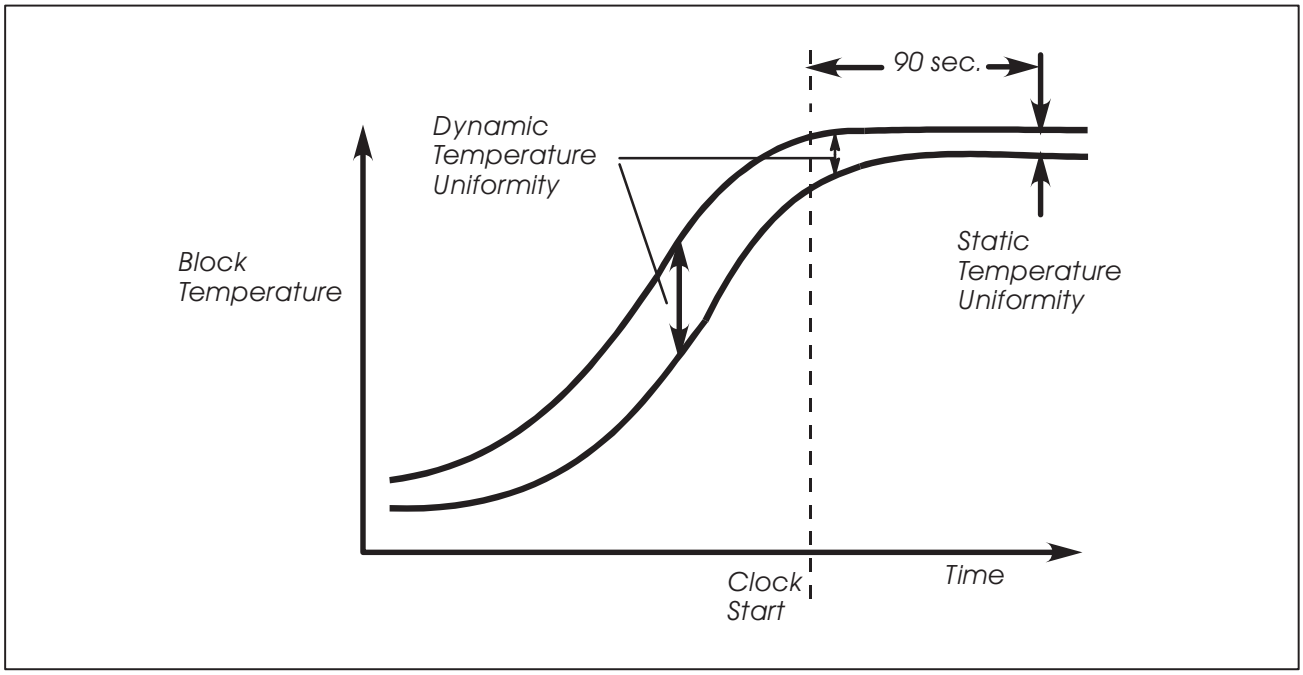


Figure 4.1: Static and dynamic block temperature uniformity while ramping up.

Block Temperature Overshoot and Undershoot

The LCx Thermal Cycler temperature display overshoots the target temperatures of the sample block by:

- less than 0.5°C after ramping up
- less than 2°C after ramping down (undershoot).

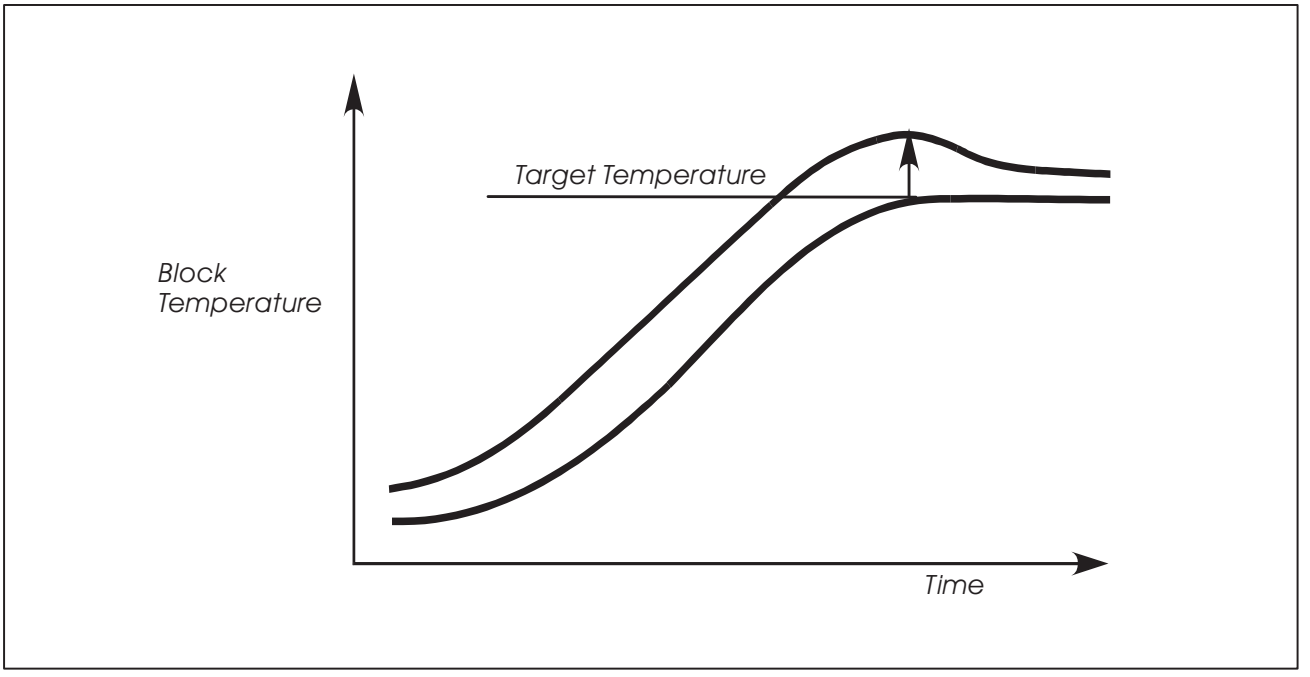


Figure 4.2: Block temperature overshoot after ramping up.

Temperature Calibration

The LCx Thermal Cycler has been calibrated at the factory to standards that are traceable to NIST.

Ramp Time and Rate

Ramp Time Reproducibility

- accurate to within five seconds

Ramp Rate

- approximately 1°C per second for heating and cooling

System Features

- Four default files, including preprogrammed Soak, Time Delay, Thermo-Cycle, and Step-Cycle files
- Available memory for up to 93 user files
- Up to 16 temperatures per repeat pattern
- Up to 99 cycles per repeat pattern
- Infinite post-amplification subambient incubation
- Sub-zero incubation for freeze-thaw cycling

NOTES

Operating Instructions
Section Table of Contents

Displays and Function Keys

Overview

This section of the manual provides step-by-step instructions for programming and performing nucleic acid amplification. It will lead you through the steps necessary in:

- System Set Up
- Accessing files
- Editing and storing files
- Loading/Running samples
- Aborting a run
- Deleting files
- Accessing user files through the file directory
- Accessing main system functions
- Navigating through the files

NOTES

Files

Set Up

1. Place your LCx Thermal Cycler in the amplification and detection area.
2. Plug the LCx Thermal Cycler into a three-prong, grounded outlet. Do not use an extension cord.

⚠ **WARNING:** Before you turn the instrument on for the first time at installation, be sure that the instrument has been upright for at least four hours at normal room temperature (15°C to 30°C).

3. Allow the thermal cycler to warm up for 15 minutes after turning power ON prior to use.
4. Set up the LCx Thermal Cycler according to the steps in Section 2: *Installation Procedures and Special Requirements*.

⚠ **WARNING:** Wear clean laboratory gloves while performing any procedure with the LCx Thermal Cycler.

5. Perform the daily maintenance procedures described in **Section 9:** ***Service and Maintenance*****, Subsection:** ***Daily Maintenance***.

Accessing a File

You can only access the main system functions from the first display in a file. At power-up, the first display in the Step-Cycle file appears. If you are in the middle of a file, press the **STOP** key twice to return to the first display of that file. You can access any other file from the first display in any file by pressing:

[FILE]
File Number
[ENTER]

The first display in the file will appear on the screen.

You will use the same procedure to access both default files and user files.

Editing a File

You can edit a file by changing the amplification parameters of an existing file. You will set the amplification parameters for each assay according to its assay-specific package insert. Each assay-specific package insert contains the following information:

- Segment temperatures
- Segment duration
- Hold temperature
- Hold time
- Number of times a cycle will be repeated
- File number
- "Link to" file number
- Soak file temperature

To edit a file:

1. Refer to the assay-specific package insert for the amplification parameters.
2. If the Soak file temperature specified in the assay-specific package insert is not 25°C, edit the soak file using the procedure described in Table 5.1: Editing an X°C Soak File.

CAUTION: Do not overwrite the existing Soak file(s).

3. Access the Step-Cycle File #4 as described in Table 5.2: Editing a Step-Cycle File in this section.
4. Edit the Step-Cycle file, #4 to program the thermal cycler using the amplification parameters contained in the assay-specific package insert.

WARNING: It is necessary to use the exact amplification parameters which are listed in the assay-specific package insert. Failure to use the exact parameters leads to erroneous results and invalidates the run.

5. Keep a record of the User and File Numbers for the assay.

Editing a Soak File

Table 5.1: Editing an X°C Soak File

Display	Keystroke	Task
`STEP-CYCLE FILE` `STEP to edit file#`	**FILE, 1, ENTER,**	Access Soak file
`SOAK FILE` `STEP to edit file#`	**STEP**	Access specific Soak file
`Soak Temperature` `(-5 to 100)  25°C`	Desired soak temperature, **ENTER**	Set to desired soak temperature
`End of file` `RUN-STORE-PRINT`	**NO, ENTER**	Store setting
`File Store` `Enter User #`	User Number, **ENTER**	Record User #
`File Store` `Enter File #`	File Number, **ENTER**	Assign File #
`Yes to store` `User# 1  File # 99`	**YES**	Store File

NOTE: Stored Soak File #1 has a default value of 25°C. Under these conditions, the amplification product will remain at 25°C in the thermal cycler until the vials are removed.

Editing a Step-Cycle File

Table 5.2: Editing a Step-Cycle File

Display	Keystroke	Task
`STEP-CYCLE FILE #` `STEP to edit file #`	**FILE, 4, ENTER, STEP**	Access file
`Seg 1 Target Temp` `(-5 to 100) 94C`	desired target temperature, **ENTER**	Set Segment 1 Denature Temperature
`Seg 1 Segment Time` `(0-999) 1min 0sec`	desired minutes, **ENTER,** desired seconds, **ENTER**	Set Segment 1 Denature Time
`Seg 2 Target Temp` `(-5 to 100) 37C`	desired target temperature, **ENTER**	Set Segment 2 Annealing Temperature
`Seg 2 Segment Time` `(0-999) 1min 0sec`	desired minutes, **ENTER,** desired seconds, **ENTER**	Set Segment 2 Annealing Time
`Seg 3 Target Temp` `(-5 to 100) 72C`	desired target temperature, **ENTER**	Set segment 3 Hold Temperature
`Seg 3 Segment Time` `(0-999) 1min 0sec`	desired minutes, **ENTER,** desired seconds, **ENTER**	Set Segment 3 Hold Time
`Seg 4 Target Temp` `(-5 to 100) 0C`	**ENTER**	Accept Segment 4 Default Value
`Seg 4 Segment Time` `(0-999) 0min 0sec`	**ENTER, ENTER**	Accept Segment 4 Default Value
`Auto Seg. Extension` `NO-YES`	**ENTER**	Accept Default Value
`Cycle Count` `(1-99) 25`	desired number of cycles, **ENTER**	Set the number of cycles

Table 5.2: Editing a Step-Cycle File (continued)

Display	Keystroke	Task
`Link to stored file (0-99,0=SHUT-OFF) 0`	number of "Link to" file, **ENTER**	Enter "Link to" file #
`End of file RUN-STORE-PRINT`	**NO, ENTER**	Store setting
`File Store Enter User #`	User Number, **ENTER**	Record User #__*
`FILE #`	File Number, **ENTER**	Assign File #__**
`YES TO STORE`	**YES**	Store file

* Each operator should use a unique User ID number.

** It is recommended that a unique file number be assigned to an assay-specific set of amplification parameters. The system will assign the first available number. You may accept this number or change it to correspond to the assay file number referenced in the assay-specific package insert.

Correcting an Entry

Parameters that have been entered incorrectly may be corrected in one of two ways:

1. If you have entered the value but have **not** pressed **[ENTER]**, press **[CLEAR]** to clear the value.
2. If you have entered the value and have pressed **[ENTER]**, press **[HELP]** to return to the previous parameter and enter the correct value.

Confirming an Entry

Parameters

You may confirm the parameters you have entered during or after editing a file by pressing:

[FILE]
File Number
[ENTER]
[STEP] repeatedly to step through the programmed parameters
[STOP]

Verify that the parameters match the values in the assay-specific package insert.

File

WARNING: It is necessary to use the exact amplification parameters which are listed in the assay-specific package insert. Failure to use the exact parameters leads to erroneous results and invalidates the run.

You may confirm the existence of a file by accessing the File Directory and by viewing the file type and number in one of two ways – ALL or BY TYPE. See ***Using File Directory*** in this section.

Running Samples

Loading Samples

Before loading samples, verify that the thermal cycler power has been on for at least 15 minutes.

1. Place individual vials into the LCx sample block. The caps of the vials should be positioned diagonally (see Figure 5.1). This ensures that each vial is fully seated in the sample well. Verify that all amplification vial caps are tightly closed and at the same level in the sample block.

⚠ **WARNING:** If an amplification vial opens during a run, this sample will be invalid and may invalidate the run. Do not continue to process these samples. Make sure the amplification vial caps are tightly closed. Remove carefully to a biohazard bag and seal the bag. Dispose of according to waste disposal procedures in **Section 8: *Hazards,* Subsection: *Biosafety.*** Refer to your assay-specific package insert for the use of calibrators and controls. To decontaminate, refer to **Section 8: *Hazards*** and **Section 9: *Service and Maintenance***.

2. Close the sample block cover.

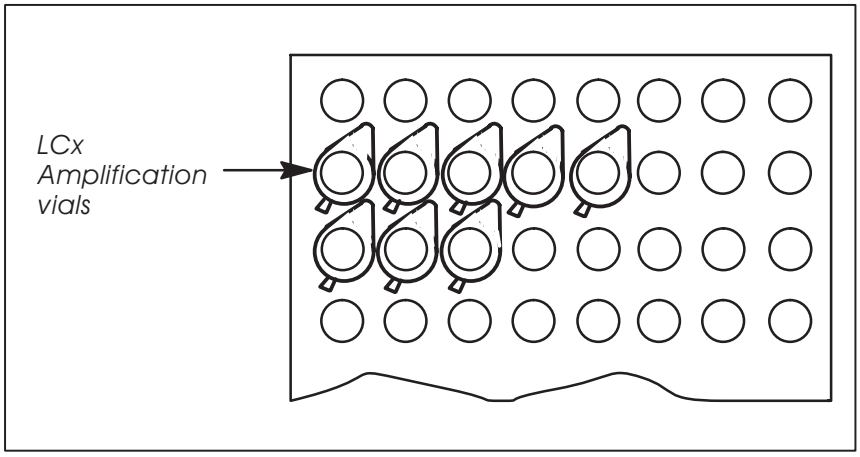


Figure 5.1:r Example of Amplification Vials loaded correctly.

Beginning a Run

The following steps describe how to begin a run:

1. To access the file you want to run, press:

   [FILE]
   File Number
   [ENTER]

2. To step through and view each file parameter, press **[STEP]**. Verify that these values match the values listed in the assay-specific package insert. When you have reached the last screen in the file, the display reads:

   ```
   End of File
   RUN-STORE-PRINT
   ```

3. To run the file, press:

   [ENTER]
   [START]
   or
   [YES]
   [START]

   A run-time display will appear as the LCx Thermal Cycler runs the file.

WARNING: It is necessary to use the exact amplification parameters which are listed in the assay-specific package insert. Failure to use the exact parameters leads to erroneous results and invalidates the run.

Aborting a Run

To abort a **Soak** file run, press:

[STOP] twice.

NOTE: A Soak file run must be aborted to terminate the run. Pressing **[STOP]** does not invalidate the run.

To abort **any other** file, press:

[STOP] three times.

WARNING:

- If you press **[STOP]** at any time during a Thermo-Cycle or Step-Cycle file run, or if the run is interrupted, the run is invalid. Do not continue to process these samples. Make sure the amplification vial caps are tightly closed. Remove carefully to a biohazard bag and seal the bag. Dispose of according to waste disposal procedures in **Section 8:** ***Hazards,*** **Subsection:** ***Biosafety.***
- Do not open amplification vials during or after thermal cycling. This increases the risk of introducing amplification products into the laboratory environment.

WARNING:

- To protect yourself against burns, do not open the sample block cover or touch the sample block when the **HOT** light is illuminated. This indicates a sample block temperature above 50°C. Do not open the sample block cover until a sample block temperature of less than 37°C is displayed.
- If the sample block cover is raised or found to have been raised during a run, the run is invalid. Do not continue to process these samples.

Unloading Samples

1. When cycling has been completed, interrupted, or aborted, remove the amplification vials from the thermal cycler making sure the amplification vial caps are tightly closed.

CAUTION: If the run was aborted or interrupted, remove the amplification vials carefully to a biohazard bag and seal the bag. Dispose of according to waste disposal procedures in **Section 8:** ***Hazards,*** **Subsection:** ***Biosafety.***

WARNING: Perform amplification product inactivation on racks used to transport samples from Specimen Preparation (Area 1) to Amplification and Detection (Area 2) before removing racks from Area 2.

- Refer to the procedure described in **Section 8:** ***Hazards*** and **Section 9:** ***Service and Maintenance.***
- Dispose of all clinical specimens, reagents, controls, calibrators, and disposables that may be contaminated, in accordance with local, state, and federal regulations governing the treatment of regulated medical wastes.

WARNING: If an amplification vial opens during a run, this sample is invalid and should not be used. Do not continue to process these samples. Make sure the amplification vial caps are tightly closed. Remove carefully to a biohazard bag and seal the bag. Dispose of according to waste disposal procedures in **Section 8:** ***Hazards,*** **Subsection:** ***Biosafety.*** Refer to your assay-specific package insert for the use of calibrators and controls. To decontaminate, refer to **Section 8:** ***Hazards*** and **Section 9:** ***Service and Maintenance.***

CAUTION: Verify by visual inspection that no liquid is in the cap of the amplification vial prior to detection. If appropriate, the amplification vials may be centrifuged in a micro centrifuge. Refer to your assay-specific package insert for centrifugation requirements.

Deleting a File

To delete a user file, you can press **[FILE]** and **[CLEAR]** or you can *overwrite* the file. You cannot delete a default file.

Using File & Clear keys

1. Access the file you want to delete by pressing

   [FILE]
   File Number
   [ENTER]

2. At the first display in the file, press:

   [FILE]
   [CLEAR]
   [YES]

3. Enter the file number of the next file you want to access and press **[ENTER]**.

Overwriting

You can also delete a file by following these steps to overwrite it.

1. Access the file you want to delete by pressing:

   [FILE]
   File Number
   [ENTER]

2. Change any parameters of the file to create a new user file according to the assay-specific package insert.

3. Go to the last display in the file. Press:

   [NO]
   [ENTER]
   User Number
   [ENTER]
   File Number
   [ENTER]
   [YES]

4. Verify the parameters against values in the assay-specific package insert. Update your User Number and File Number records.

NOTES

File Directory

Accessing File Directory

When the first display in any file appears on the screen, you can access the File Directory by pressing:

[FILE]
[ENTER]

The File Directory display will appear:

```
File Directory
ALL-BY TYPE-BY USER
```

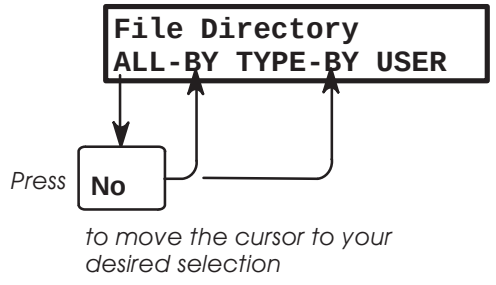
Using File Directory

The File Directory display lets you select a directory to view.

- ALL permits you to view a directory of all stored files, listed in numerical order.
- BY TYPE permits you to view all stored files of a particular type, for example, all Soak files, all Time Delay files, all Thermo-Cycle files, or all Step-Cycle files.
- BY USER permits you to view all stored files with the same user number.

You can select the kind of directory you want to view here.

1. Press **[NO]** to move the cursor to your selection, then **[ENTER]** to select.



Viewing All Files

The following display appears when you select ALL:

```
File Directory
Enter first file#
```

1. Enter the number of the first file you want to view, then press **[ENTER]**.

   For example, if you press **[1]** then **[ENTER]**, you will see a display that shows the name and file number (1) of the first file in the directory.

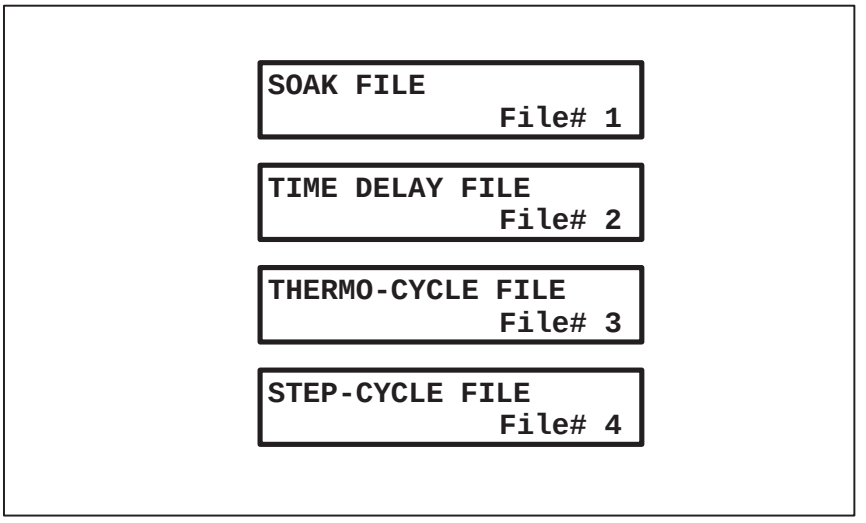


Figure 5.2: Example of ALL file directory.

2. To move forward through the displays, press **[STEP]**.
3. After all the files have been displayed, you can exit the File Directory and go directly to any file from this display:

   ```
   Directory complete
   Enter new file#
   ```

   Press:

   File Number
   [ENTER]

Viewing by File Type

The following display appears when you select BY TYPE:

```
File Directory
Enter file type#
```

1. Press the numeric key corresponding to the file number of the TYPE of files you want to view:
   - **1** – to view all Soak files
   - **2** – to view all Time Delay files
   - **3** – to view all Thermo-Cycle files
   - **4** – to view all Step-Cycle files
2. Press **[ENTER]**.

   All files of the particular type will appear by file number in numerical order.

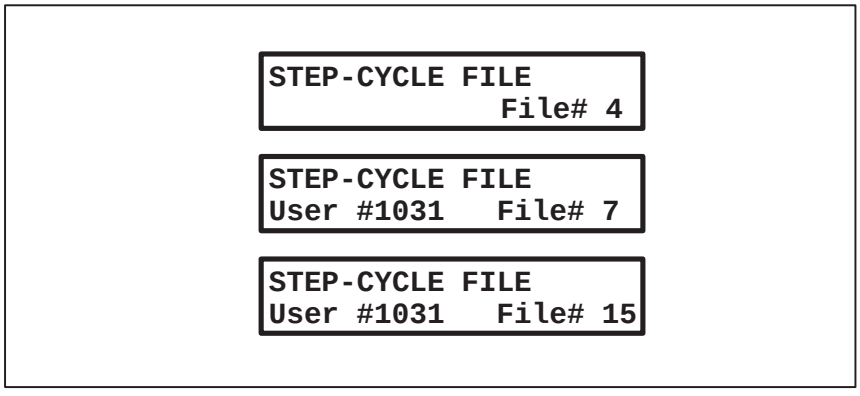


Figure 5.3: Example of BY TYPE file directory.

3. To move forward through the displays, press **[STEP]**.
4. After all the files have been displayed, you can exit the File Directory and go directly to any file from this display:

```
Directory complete
Enter new file#
```

Press:

File Number
[ENTER]

Viewing by User Number

The following display appears when you select BY USER:

```
File Directory
Enter user #
```

1. Press:

   User Number
   [ENTER]

   All files with that user number will appear sequentially by file number.

2. To move forward through the displays, press **[STEP]**.

3. After all the files have been displayed, you can exit the File Directory and go directly to any file from this display:

   ```
   Directory complete
   Enter new file#
   ```

   Press:

   File Number
   [ENTER]

Quality Control Program

For optimal performance, Abbott Laboratories recommends the following Quality Control Program for amplifying samples in the LCx Thermal Cycler:

- Maintain the LCx Thermal Cycler according to the instructions and schedules provided in **Section 9:** ***Service and Maintenance***. Regular maintenance minimizes system problems and maximizes thermal cycler performance.
- Use assay-specific controls to monitor the performance of the LCx Thermal Cycler and to monitor the performance of the LCx Analyzer, reagents and assay procedures. For assay-specific control recommendations, which may vary between assays, refer to the assay-specific package insert.

⚠ **CAUTION:** Abbott Laboratories cannot accept responsibility for the accuracy of any results if amplification vials or amplification reagents manufactured by anyone other than Abbott Laboratories are used.

NOTE: If quality control procedures for your laboratory require you to use controls more frequently than the assay-specific package insert recommends, follow the requirements established by your laboratory.

NOTES

Main System Functions

Accessing Main System Functions

The LCx Thermal Cycler has the following system features and functions which are accessible to the user:

- Default & User Files
- File Directory
- Configuration
- Diagnostics

Figure 5.4 illustrates how to access the main functions of the LCx Thermal Cycler.

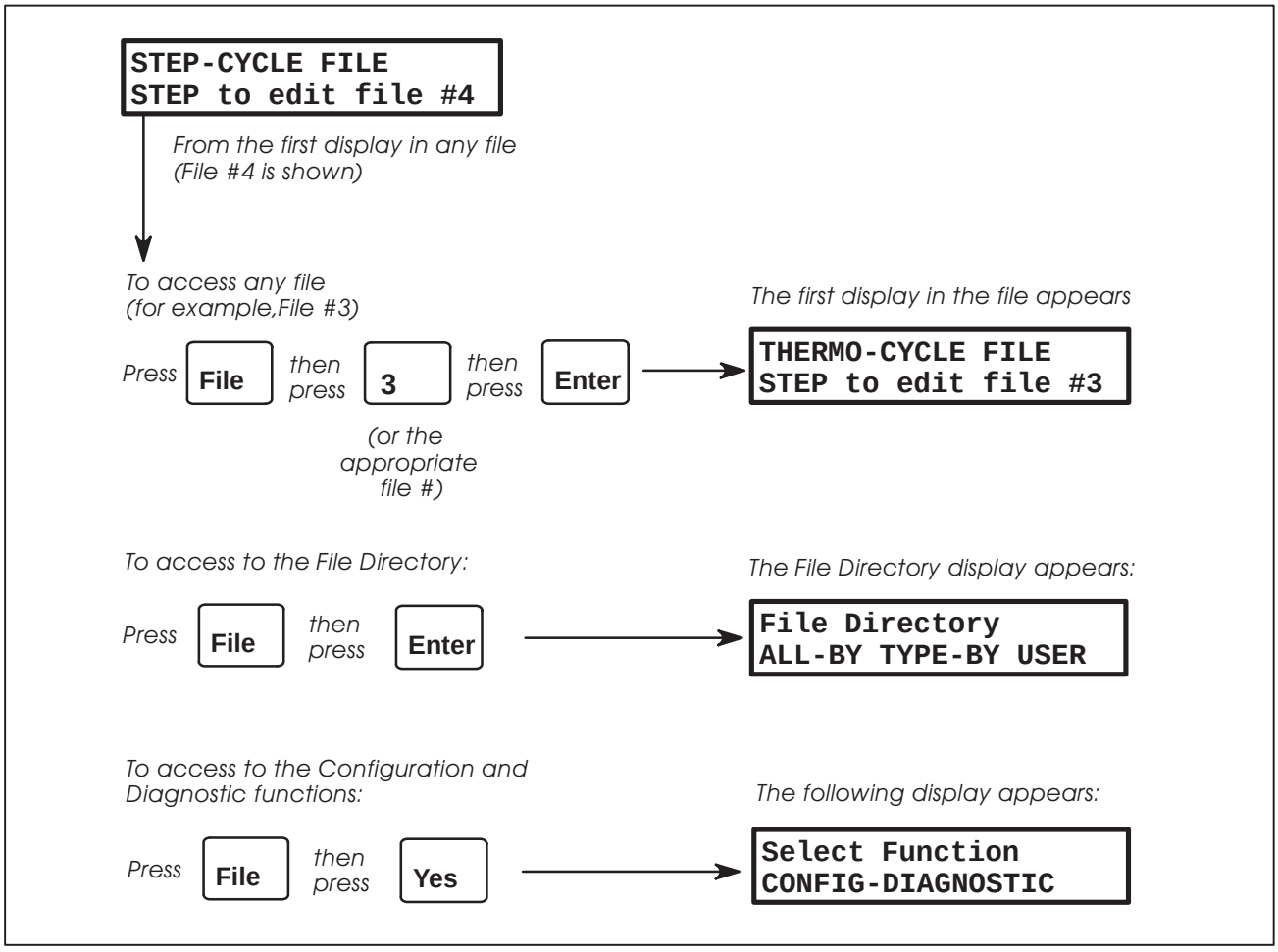


Figure 5.4: Accessing the main system functions

NOTES

Displays and Function Keys

Displays

The following flow diagram will help guide you through the LCx Thermal Cycler display screens.

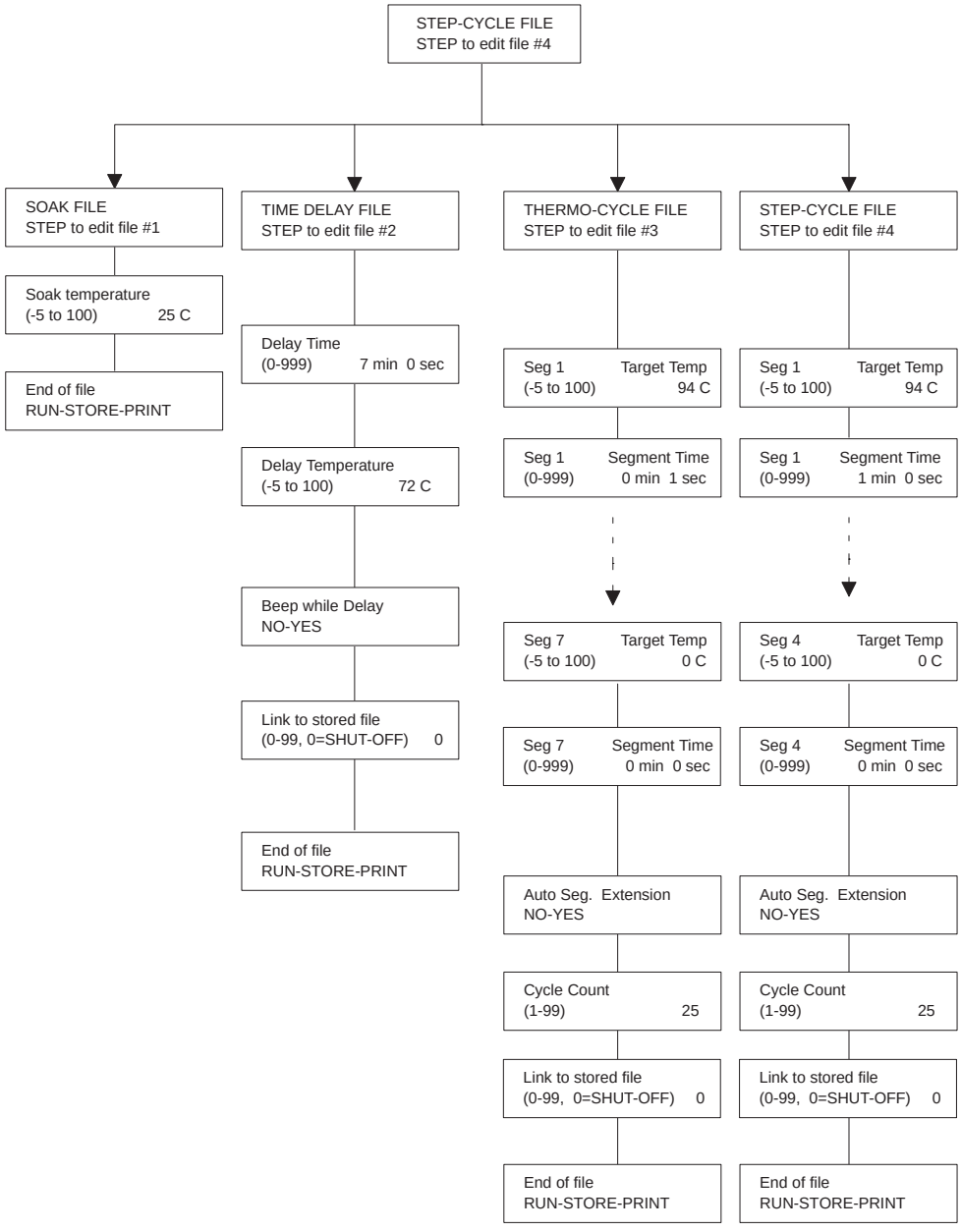


Figure 5.5: Display Sequence Flow Diagram

Power-Up

When you first turn on the LCx Thermal Cycler, the following display appears on the screen:

```
STEP-CYCLE FILE
STEP to edit File #4
```

This is the first display in File #4, the Step-Cycle file (It is one of the default files).

All the main system functions are accessible from the first display in each file. From this display you can:

- access any file
- access the File Directory
- access the Configuration and Diagnostic functions
- run the file
- edit the parameters in the file, and store the new parameters as a new or existing user file

Step-Cycle File

The Step-Cycle file is not used for all assays. Refer to the assay-specific package insert for the assay you are running. A Step-Cycle file usually has three segments per cycle and can have up to 99 cycles.

In the Step-Cycle file you can set the target temperatures for thermal plateaus and hold times in minutes and seconds for segments display 1, 2 and 3.

The Step-Cycle file is used to:

- set the target temperature for the terminating segment
- extend a segment
- specify the number of times your thermal profile will be repeated
- link the Step-Cycle file to another file

WARNING: It is necessary to use the exact amplification parameters which are listed in the assay-specific package insert. Failure to use the exact parameters leads to erroneous results and invalidates the run.

Thermo-Cycle File

The Thermo-Cycle file is not used for all assays. Refer to the assay-specific package insert for the assay you are running. In a Thermo-Cycle file, there are usually six active segments and one terminating segment. A typical Thermo-Cycle file has six segments for a three-temperature amplification:

- Segments #1 and #2 - Denaturing
- Segments #3 and #4 - Annealing
- Segments #5 and #6 - Extending or gap-filling and ligation

A Thermo-Cycle file can have up to 99 cycles.

The Thermo-Cycle displays are used to:

- set target temperatures for thermal transitions and plateaus and for ramp and hold times
- extend a segment
- designate a terminating segment
- set cycle count
- link a Thermo-Cycle file to another file
- run a file
- store an edited Thermo-Cycle file

Cycle File Run-Time

Thermo-Cycle and Step-Cycle files have the same type of run-time displays. The primary run-time display in both of these files shows:

- the current temperature of the sample block
- the amount of time remaining in the current segment
- the number of cycles remaining in the file
- the programmed target temperature in the current segment. Refer to Figure 5.6.

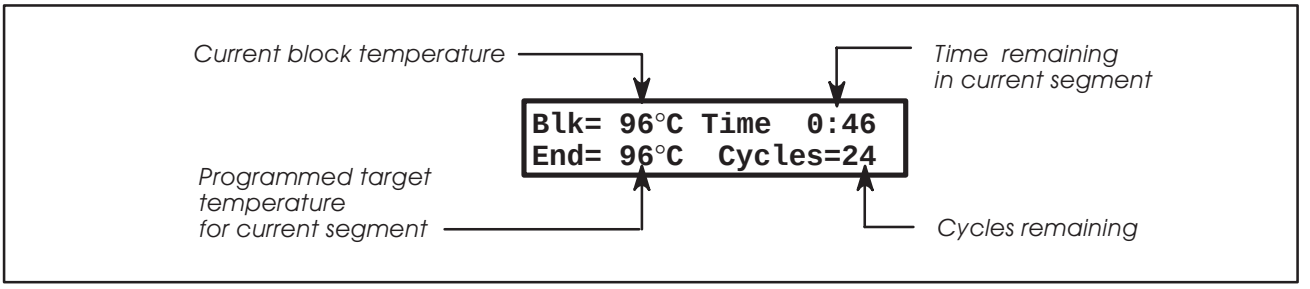


Figure 5.6: An example run-time display in a Cycle file.

There is a secondary run-time display in both cycle files that can be viewed by pressing the **Help** key. A display similar to the one shown in Figure 5.7 appears.

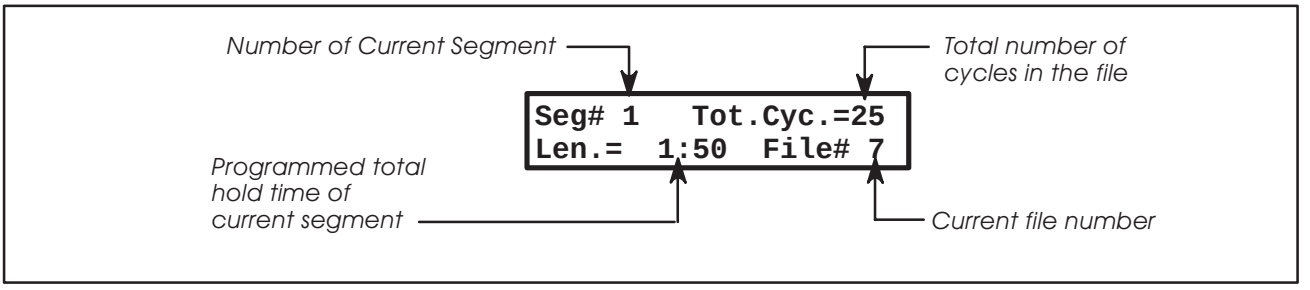


Figure 5.7: Secondary run-time display in a Cycle file.

The **Help** key returns you to the first run-time display.

Block Temperature Display

You can view the current temperature of the sample block by pressing the **Help** key from the first display in a file, or at the end of a run. The screen displays:

```
Block Temp= 31°C
```

Press any function key (for example, **Step**) to return to the first display in the file.

Time Delay File

The Time Delay file is not used for all assays. Refer to the assay-specific package insert for the assay you are running. The Time Delay file is used to:

- set the number of minutes and seconds in the delay time
- set the block (delay) temperature of a file
- activate a beeper
- link a Time Delay file to another file
- run the file
- store an edited Time Delay file

Run-time Displays

The first run-time display in a Time Delay file shows the current temperature of the sample block and the amount of time left in the run (see Figure 5.8).

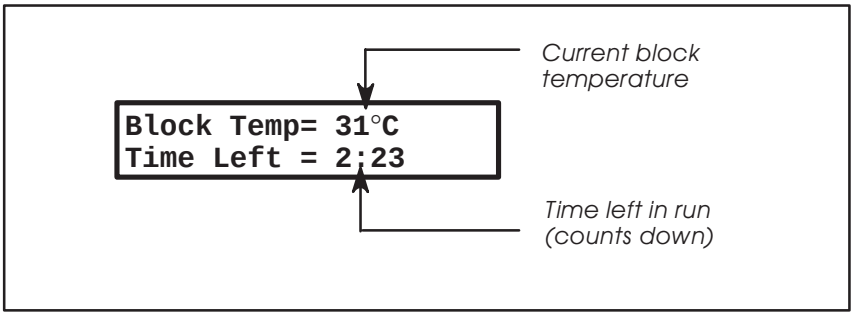


Figure 5.8: An example run-time display in a Time Delay file.

There is a secondary run-time display in a Time Delay file that you can view by pressing the **Help** key.

The secondary run-time display shows the programmed target temperature, the programmed delay time, and the file number of the file that is being run.

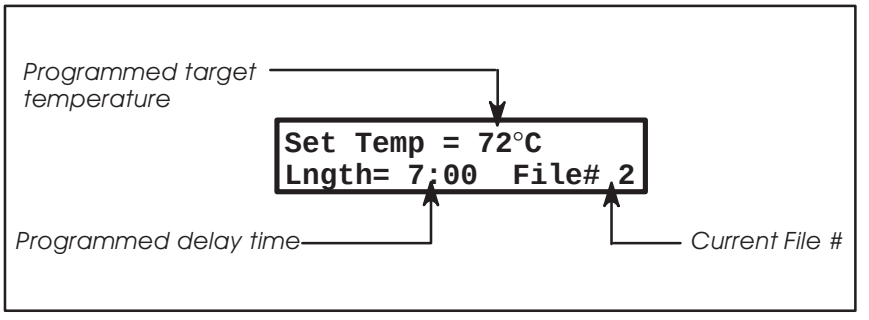


Figure 5.9: A secondary run-time display in a Time Delay file.

Soak File

The Soak File is used to:

- set the sample block (soak) temperature
- run the soak file
- store an edited soak file

Run-time Display

The run-time display in a Soak file provides status information. It shows the target temperature, the current temperature of the sample block, and the current elapsed time (see Figure 5.10).

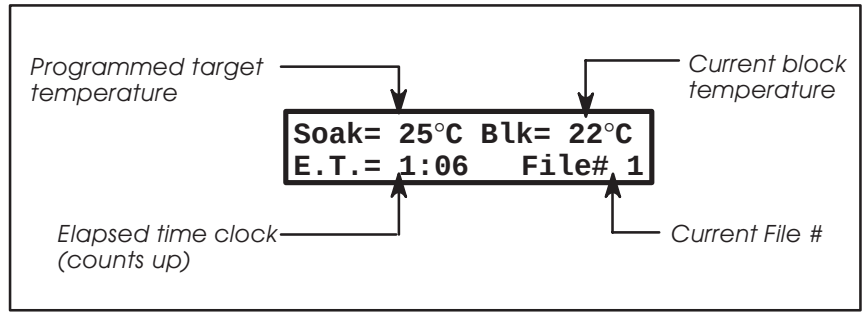


Figure 5.10:p An example of a run-time display in a Soak file.

Configuration File

The Configuration file contains two parameters:

- The pause time-out limit is the time the thermal cycler pauses after the **Stop** key is pressed. The pause time-out limit should not be edited.

⚠ **WARNING:** If the thermal cycler run is interrupted or aborted, the run is invalid. Do not continue to process these samples. Make sure the amplification vial caps are tightly closed. Remove carefully to a biohazard bag and seal the bag. Dispose of according to waste disposal procedures in **Section 8:** ***Hazards,*** **Subsection:** ***Biosafety.***

- The printer mode selection allows you to turn on the printer mode to get printouts of file parameters or run-time data.

Function Keys

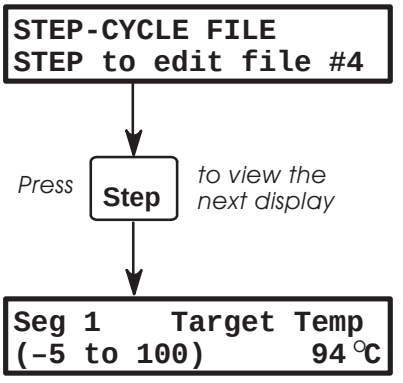
Start

The **Start** key begins a run from the first display in a file.

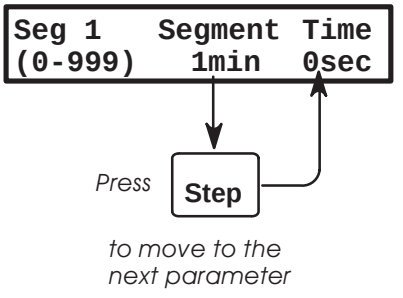
Step

The **Step** key enables you to:

- view the next display in a file



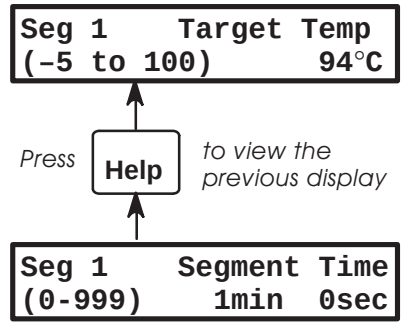
- accept a default value and move to the next parameter when editing a file:



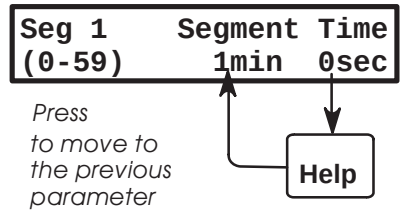
Help

The **Help** key enables you to:

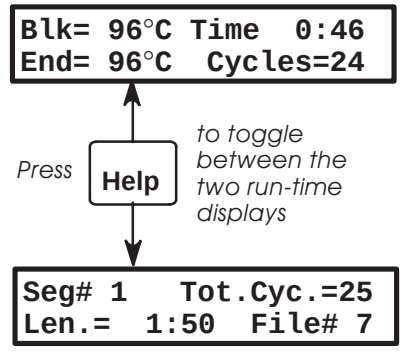
- view the previous display in a file:



- move to the previous parameter when editing a file:



- toggle between the two run-time displays when running samples:



Stop

While editing a file:

- press the **Stop** key once to move to the last display in a file.
- press the **Stop** key twice to move to the first display in that file.

While performing other functions, press the **Stop** key:

- **Once** to pause a run in progress
- **Twice** to abort a Soak file run
- **Three times** to abort a Time Delay, Thermo-Cycle, or Step-Cycle file run in progress

⚠ **WARNING:** If you press **[STOP]** at any time during a thermal cycler run, the run is invalid. Do not continue to process these samples. Make sure the amplification vial caps are tightly closed. Remove carefully to a biohazard bag and seal the bag. Dispose of according to waste disposal procedures in **Section 8:** ***Hazards,*** **Subsection:** ***Biosafety.***

File

The **File** key in combination with:

- a numeric key and the **Enter** key may be used to access a file:

  Press **File** *then press* **4** *then press* **Enter**

- the **Enter** key to access the File Directory:

  Press **File** *then press* **Enter**

- the **Yes** key to access the Configuration and Diagnostic functions:

  Press **File** *then press* **Yes**

- the **Clear** key to delete a file whose first display currently appears on the screen:

  Press **File** *then press* **Clear**

Yes

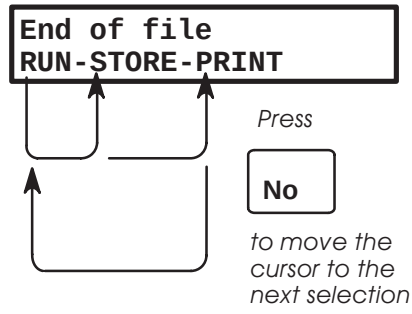
The **Yes** key:

- stores a newly created file.
- completes the deletion of a file initiated by the **File** and **Clear** key sequence.
- overwrites a file number that was used previously.

No

The **No** key enables you to:

- move the cursor on a display from one selection to the next:



- enter negative values from –5° to –1°C, for example, to enter a temperature of –5°C, press **No**, then **5**, then **Enter**.

Enter

The **Enter** key enables you to:

- accept a displayed value and move to the next parameter.
- accept a selection, e.g., RUN, and initiate that operation.

Clear

The **Clear** key clears the current value from the display.

- The **Clear** key used in combination with the **File** key deletes the file whose first display currently appears.

Press **File** *then press* **Clear**

Numeric Keys

Numeric Keys assign values for amplification parameters and for file and user numbers.

NOTES

Calibration Procedures

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NOTES

Overview

The LCx Thermal Cycler is calibrated prior to delivery. This section describes the Temperature Calibration procedure which may be required after the Temperature Calibration Verification test. Refer to **Section 9:** ***Service and Maintenance,*** **Subsection:** ***Temperature Calibration Verification Test.***

NOTES

Temperature Calibration

The Temperature Calibration procedure is used to calibrate the temperature control of the LCx Thermal Cycler. Temperature Calibration is performed only after Temperature Calibration Verification fails.

Compute the sample block temperature (T_{avg} @ 40°C and @ 95°C) using the Temperature Calibration Verification test described in **Section 9:** ***Service and Maintenance***. If the values of T_{avg} @ 40°C or T_{avg} @ 95°C differ from the target temperature by more than ±1°C, perform the Temperature Calibration procedure as follows:

1. From the first display in any file, press:

   [STEP]
   [STOP]
   [HELP]

2. Wait 2 seconds, then press:

   [YES]
   [STEP]
   [1]
   [START]

3. Monitor and input calibration data displayed by the thermal cycler as described in Table 6.1.

Table 6.1: Calibration Data Entry Procedure

Display	Target Temperature	Hold Time (in minutes)	Instrument/Operator Action
`Setting LOW temp...` `End= 40C  Blk= xxC`	40°C		*Sample block temperature reaches 40°C.*
`ENTER CAL temp = xxxC` `Time=  :xx  Blk= 40C`		3:00	When time equals 3 minutes in 40°C calibration hold: • Input T_{avg} @ 40 in tenths (e.g., 39.8 is entered as 398)* • Press **[ENTER]**
`Setting HIGH temp...` `End= 95C  Blk= xxC`	95°C		*Sample block temperature reaches 95°C.*
`ENTER CAL temp = xxxC` `Time=  :xx  Blk= 95C`		3:00	When time equals 3 minutes in 95°C Calibration hold: • Input T_{avg} @ 95 in tenths* • Press **[ENTER]**

*T_{avg} is computed in the Temperature Calibration Verification test.

4. When the temperature calibration procedure is complete, perform the Temperature Calibration Verification procedure. After completing the verification test, cross out, sign and date the original Low Cal and High Cal values and enter the new Low Cal and High Cal values on the calibration label. The LCx Thermal Cycler does not include extra calibration labels. Refer to **Section 9:** ***Service and Maintenance,*** **Subsection:** ***Temperature Calibration Verification Test.***

Operational Precautions & Limitations

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NOTES

Overview

This section describes limitations of the LCx Thermal Cycler that may impact amplification and hence, assay performance.

NOTES

Precautions

Instrument Cover

WARNING: Electrical Shock Hazard. There are high voltages inside the instrument. Do not remove or open the instrument cover. There are no components inside the LCx Thermal Cycler that you can safely service yourself. If you suspect a problem, contact LCx CSC.

Sample Block Cover

WARNING: To protect yourself against burns, do not open the sample block cover or touch the sample block when the **HOT** light is illuminated. This indicates a sample block temperature above 50°C. Do not open the sample block cover until a block temperature of less than 37°C is displayed.

To protect samples and guarantee temperature uniformity, the sample block cover must remain closed at all times during thermal cycling.

WARNING: If the sample block cover is raised or found to have been raised during a run, the run is invalid. Do not continue to process these samples. Make sure the amplification vial caps are tightly closed. Remove carefully to a biohazard bag and seal the bag. Dispose of according to waste disposal procedures in **Section 8:** ***Hazards,*** **Subsection:** ***Biosafety.***

Grounding & Electrical Safety

WARNING: Electrical Shock Hazard. The LCx Thermal Cycler must be grounded for protection against electrical shock. Use a three-prong, grounded outlet. Do not use an adapter to a two-terminal outlet since this does not provide positive ground protection. Do not use an extension cord.

Electrical Safety Testing

Routine safety testing of analytical instruments (e.g., high potential voltage testing) may be required by law.

Testing should only be conducted by qualified personnel.

Certain main supply surge suppressor components may need to be disconnected prior to performing a test. These must be reconnected upon completion.

Contact LCx CSC before performing any AC line tests.

Fuses and Power Interruption

If instrument power is interrupted while the instrument is running, turn the LCx Thermal Cycler off and wait five minutes before turning the power back on. If power restoration occurs within five minutes, a fuse may blow.

⚠ **CAUTION:** If the thermal cycler run is interrupted or aborted, the run is invalid. Do not continue to process these samples. Make sure the amplification vial caps are tightly closed. Remove carefully to a biohazard bag and seal the bag. Dispose of according to waste disposal procedures in **Section 8:** ***Hazards,*** **Subsection:** ***Biosafety.***

Use of Abbott Laboratories Products

Abbott Laboratories cannot accept responsibility for the accuracy of any results if amplification vials or amplification reagents manufactured by anyone other than Abbott Laboratories are used.

Limitations

Temperature, Humidity, and Environment

The LCx Thermal Cycler must be operated at an ambient temperature of 15° to 30°C (59° to 86°F), an ambient relative humidity of 20 to 80% (without condensation) and at an altitude of 0 to 2,000 meters (6,562 feet).

Electromagnetic Compatibility (EMC)

United States (FCC)

This product is classified as a digital device used exclusively as industrial, commercial, or medical test equipment. It is exempt from the technical standards specified in Part 15 of the FCC Rules and Regulations, based on Section 15.103 (c).

Japan (FCC)

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. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

European Union (EMC Directive)

This product has passed the following EMC tests:

VDE 0871B
EN 55011 : 91
IEC 801-2 : 84
IEC 801-3 : 84
IEC 801-4 : 88

NOTES

Hazards
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NOTES

Overview

This section provides information about hazards that might be encountered while operating the LCx Thermal Cycler. Failure to take precautions to avoid these hazards could result in personal injury or damage to the laboratory. Hazards are defined and instructions for prevention of and response to individual hazards are provided.

NOTES

Emergency Shutdown Procedure

The emergency shutdown procedure follows:

1. Turn the power switch on the front of the LCx Thermal Cycler to OFF.
2. Disconnect the power cord to prevent electrical shock to the operator or damage to the thermal cycler.

NOTE: When the power is turned off, all system and assay file information is retained in memory.

NOTES

Biosafety

General Warning

Consider all specimens, controls, calibrators, and amplification vials that are human sourced as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910.1030) or other equivalent biosafety procedures.

Waste

Dispose of all clinical specimens, reagents, controls, calibrators, and disposables that may be contaminated, in accordance with local, state, and federal regulations governing the treatment of regulated medical wastes.

Sharps must be placed in an appropriately marked, puncture-resistant container prior to treatment and disposal.

Generally accepted procedures for the treatment of potentially infectious solid wastes include incineration or autoclaving. If an autoclave is used, you should verify the effectiveness of the decontamination cycle.

Liquid waste containing acid should be neutralized prior to the addition of a disinfectant and disposal.

Spills

Clean up spills of potentially infectious materials in accordance with established biosafety practices. A generally accepted procedure for cleaning such spills is to absorb the spill with toweling or other absorbent material, wipe the area with a detergent solution, and then wipe the area with an appropriate tuberculocidal disinfectant such as 0.5% sodium hypochlorite (10% chlorine bleach).

If there is a need to inactivate amplification product, a 1.0% sodium hypochlorite solution (20% chlorine bleach) should be used.

NOTES

Decontamination Procedures

Perform decontamination procedures prior to servicing or shipping the LCx Thermal Cycler or Temperature Verification System.

NOTE: Throughout this manual a tuberculocidal disinfectant such as 0.5% sodium hypochlorite (10% chlorine bleach) is recommended for biohazard decontamination and 1.0% sodium hypochlorite (20% chlorine bleach) is recommended for amplification product inactivation.

NOTE: Wear clean laboratory gloves while performing any procedure with the LCx Analyzer.

Thermal Cycler Surfaces

To decontaminate thermal cycler surfaces:

1. Turn thermal cycler power off.
2. Wipe the surface of the thermal cycler with a detergent solution to remove any soiling.
3. Wipe the unit down with a tuberculocidal disinfectant such as 0.5% sodium hypochlorite (10% chlorine bleach).
4. Wipe the surface with a 70% ethanol solution and let dry.

NOTES

Amplification Product Inactivation Procedures

To prevent DNA contamination, perform amplification product inactivation as part of lab maintenance and also when removing equipment from Area 2. Amplification vials from aborted runs or amplification vials found open must be closed tightly and sealed in a biohazard bag. Dispose of the biohazard bag according to Waste Disposal procedures in this section.

> **NOTE:** Chlorine solutions may pit equipment and metal. Remove chlorine with sufficient amounts or repeated applications of 70% ethanol until all chlorine bleach residues are no longer visible.

Work Surfaces

Surface cleaning using 1.0% sodium hypochlorite (20% chlorine bleach) followed by 70% ethanol should be performed on bench tops on a routine basis.

Tube Racks

Perform the following procedure before moving tube racks from Area 2.

Soak tube racks in a 1.0% sodium hypochlorite solution (20% chlorine bleach) for a minimum of 10 minutes. Rinse with water.

Thermal Cycler Surfaces

Wipe equipment surfaces with 1.0% sodium hypochlorite solution (20% chlorine bleach). Rinse thoroughly with 70% ethanol.

NOTES

General Precautions

Electrical

To avoid damage to the thermal cycler, do not disconnect any electrical connection while the power is on.

Mechanical

Keep hands away from the sample block while the thermal cycler is operating.

NOTES

Instrument Hazards

Sample Block Cover

WARNING: When the **HOT** light is illuminated, the temperature of the sample block is greater than 50°C. Do not open the sample block cover or touch the sample block when the **HOT** light is illuminated. Do not open the sample block cover until a block temperature of less than 37°C is displayed.

NOTES

Electrical Hazards

The LCx Thermal Cycler must be grounded to protect against electrical shock. Use a three-prong, grounded outlet. Do not use an extension cord. An adapter to a two-terminal outlet does not provide positive ground protection.

⚠ **WARNING:** To avoid exposure to high voltages do not remove or open the instrument cover. There are no user-serviceable components inside the instrument.

Disconnect the power cord before cleaning, decontaminating or servicing to prevent electrical shock to the operator or damage to the thermal cycler.

NOTES

Service and Maintenance
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NOTES

Overview

This section describes routine maintenance and provides performance schedules for the recommended maintenance procedures.

Regularly scheduled cleaning and system checks keep the LCx Thermal Cycler performing properly.

Proper maintenance of the LCx Thermal Cycler:

- Provides the best operating level for your LCx Thermal Cycler.
- Provides records for inspection.
- Indicates when adjustments or repairs are necessary prior to test results being affected. In this section, you will become familiar with the maintenance schedule and procedures recommended by Abbott Laboratories for the LCx Thermal Cycler.

There are no user serviceable parts, call LCx CSC if instrument service is required.

NOTES

Daily Maintenance

Chiller Test

The Chiller and Heater tests should be run daily to check the performance of the cooling and heating systems prior to thermal cycling operations.

The Chiller Test cools the block and measures the maximum cooling rate of the instrument. This test should be run only after the instrument has been idle for at least 30 minutes.

Table 9.1: Chiller Test Procedure

Display	Keystrokes	Task
First display of any file	**FILE, YES**	Access the Configuration-Diagnostic option
`Select Function` `CONFIG-DIAGNOSTIC`	**NO, ENTER**	Access Diagnostic File
`Diagnostic Tests` `Enter test# (1-6)`	**4, ENTER**	Run the Chiller test
`Chiller Test Blk=xxC` `going to 85C`		Block warming
`Chiller Test Blk=85C` `wait 1 min... :xx`		Block temperature holds at 85ºC for 1 minute
`Chiller Test Blk=xxC` `cooling...`		Block temperature displays
`Cool Rate=1.18º /sec`		Test complete
	STOP	Exit Chiller test
`Diagnostic Tests` `Enter test# (1-6)`	Test Number or **STOP**	Run another Diagnostic test or Exit Diagnostic File

The cooling rate should be between 0.85°/second and 1.90°/second.

Heater Test

The Heater Test measures the maximum heating rate and the heating time in seconds required for the first 15 degrees of temperature change and displays this information.

Table 9.2: Heater Test Procedure

Display	Keystrokes	Task
The first display of any file	**FILE**, **YES**	Access Configuration and Diagnostic option
`Select Function` `CONFIG-DIAGNOSTIC`	**NO**, **ENTER**	Select Diagnostics
`Diagnostic Tests` `Enter test #  (1-6)`	**3**, **ENTER**	Run Heater Test
`Heater Test Blk= xxC` `going to 35C...`		Block cooling
`Heater Test Blk= 35C` `wait 1 min...  :xx`		Block temperature reaches 35°C
`Heater Test Blk= xxC` `heating...`		Block temperature warming

Heating Rate ↓
`Heat Rate= 0.97°/sec`
`Time= 17s`
↑ *Heating Time*
		Block temperature displays

`Heat Rate= 0.97°/sec` `Time= 17s`	**STOP**	Exit Heater Test
`Diagnostic Tests` `Enter test #  (1-6)`	Test Number, **ENTER** or **STOP**	Run another Diagnostic Test or Exit Diagnostic File

Compare your results with Table 9.3. If any of the numbers displayed at the end of the test are outside the normal range, contact LCx CSC.

Table 9.3: Heater Test Results by Line Voltage

			Your heater rate should be ≥:	Your heating time should be ≤:
100 VAC	240 VAC	120 VAC	0.67 °/second	30 seconds

NOTES

Monthly Maintenance

NOTE: Chlorine solutions may pit equipment and metal. Remove chlorine with sufficient amounts or repeated applications of 70% ethanol until all chlorine bleach residues are no longer visible.

Sample Block Decontamination

This procedure is performed monthly prior to performing the temperature calibration verification test. The effect of the cleaning procedure is to eliminate build-up of dust particles, debris or amplification product in the sample wells and on the surface of the sample block.

WARNING: Disconnect power to the thermal cycler before performing the decontamination procedure.

WARNING: Potential Biohazard. The LCx Thermal Cycler should be cleaned and thoroughly decontaminated prior to shipment or transfer from one laboratory to another.

WARNING: The LCx Thermal Cycler should be cleaned and thoroughly decontaminated in the case of a spill or accidental opening of an amplification vial during thermal cycling. Refer to ***As Required Maintenance*** in this section.

1. Wipe the surface of the sample block with a tissue moistened with 20% bleach.
2. Wipe the bleach-treated surface with a tissue moistened with distilled water.
3. Dispense distilled water in each well approximately to full capacity. Swirl water with cotton swab to wash all walls.
4. Aspirate the water from each well.
5. Dispense 70% ethanol in each sample well.
6. Aspirate the ethanol from each sample well.
7. Wipe the surface of the sample block with a tissue moistened with 70% ethanol solution. Use sufficient amounts of ethanol or repeated applications of ethanol until chlorine residue is no longer visible.
8. Allow the sample block to dry.
9. Check for particulate matter in each well. If noticed, remove with a cotton swab.

Thermal Cycler Surfaces Decontamination

Cleaning thermal cycler surfaces is performed to prevent the build-up of amplification product on instrument surfaces.

WARNING: Potential Biohazard. The LCx Thermal Cycler should be cleaned and thoroughly decontaminated prior to shipment or transfer from one laboratory to another.

WARNING: The LCx Thermal Cycler should be cleaned and thoroughly decontaminated in the case of a spill or accidental opening of an amplification vial during thermal cycling. Refer to ***As Required Maintenance*** in this section.

1. Wipe the thermal cycler with a detergent solution to remove any soiling.
2. Wipe the thermal cycler with 1.0% sodium hypochlorite solution (20% chlorine bleach).
3. Rinse with a tissue moistened with distilled water.
4. Wipe the surface of the Thermal Cycler with a tissue moistened with 70% ethanol solution. Use sufficient amounts of ethanol or repeated applications of ethanol until chlorine residue is no longer visible.

Temperature Calibration Verification Test

Use this procedure to verify the temperature calibration of your Abbott LCx Thermal Cycler.

Equipment

You will need the following equipment:

Provided

- Temperature Verification System, which includes:
  - Digital Thermometer (9V battery installed) with probe
  - Temperature Verification System Operators Manual

Required (but not provided)

- A one-pound weight to keep the sample block cover closed (minimum 1 lb. (.45 Kg))

Temperature Verification System

If any supplied part of the Temperature Verification System is damaged or missing, contact the LCx CSC immediately.

Using the Temperature Verification System

The Temperature Verification System is used to verify that the LCx Thermal Cycler is still calibrated. It is also used to test the temperature uniformity of the sample block.

Refer to the operators manual provided with the Temperature Verification System for operation instructions.

WARNING: Do not try to recalibrate or perform any service on the Temperature Verification System. The only user-serviceable component in the unit is a battery. If you experience any problem with the use of the Temperature Verification System, contact the LCx CSC.

Verification Procedure

Perform the test as follows:

1. Turn the thermal cycler on and let it warm up for at least 15 minutes.
2. Create a two-temperature Step-Cycle file with the following parameters. Refer to **Section 5:** ***Operating Instructions, Table 5.2: Editing a Step-Cycle File.***

Table 9.4: Step-Cycle File Parameters

Segment	Temperature	Time (in minutes)
1	95°C	3:30
2	40°C	3:30
3	0°C	0:00
Auto Segment Extension: off Cycle Count = 99 Link to Shut-off (0)		

NOTE: Three minutes is the maximum time for the Temperature Verification System to reach maximum accuracy.

3. Place the probe into sample well C1 of the sample block. Refer to Figure 9.1.

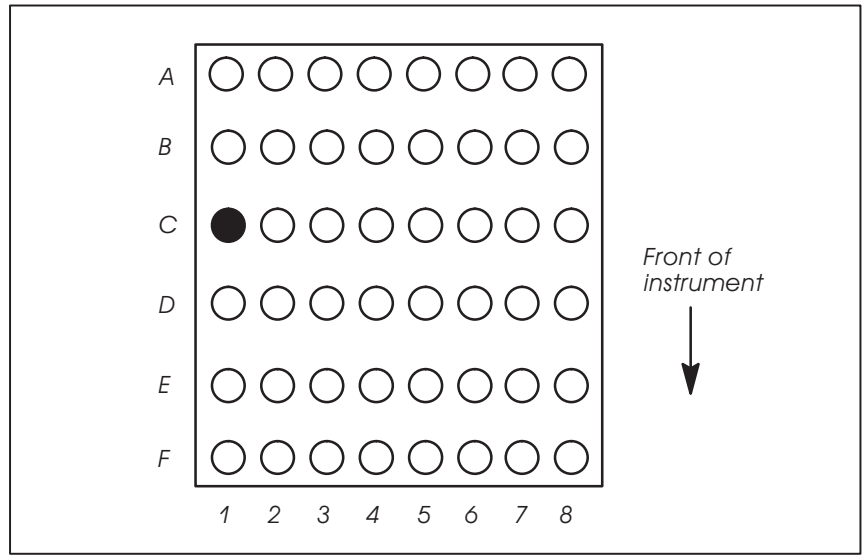

Figure 9.1: Location of sample well C1.

4. Press down firmly on the probe, close the sample block cover, and place the one-pound weight on the cover. This ensures that the probe is seated correctly in the sample well.
5. Turn on the Temperature Verification System.
6. Run the two-temperature Step-Cycle file that you set up in Step 2. At cycle 96 or lower, measure the temperature of well C1 when 30 seconds remain in both segments #1 and #2.

7. Record the segment #1 temperature as T(95). Record the segment #2 temperature as T(40) (see Figure 9.2).

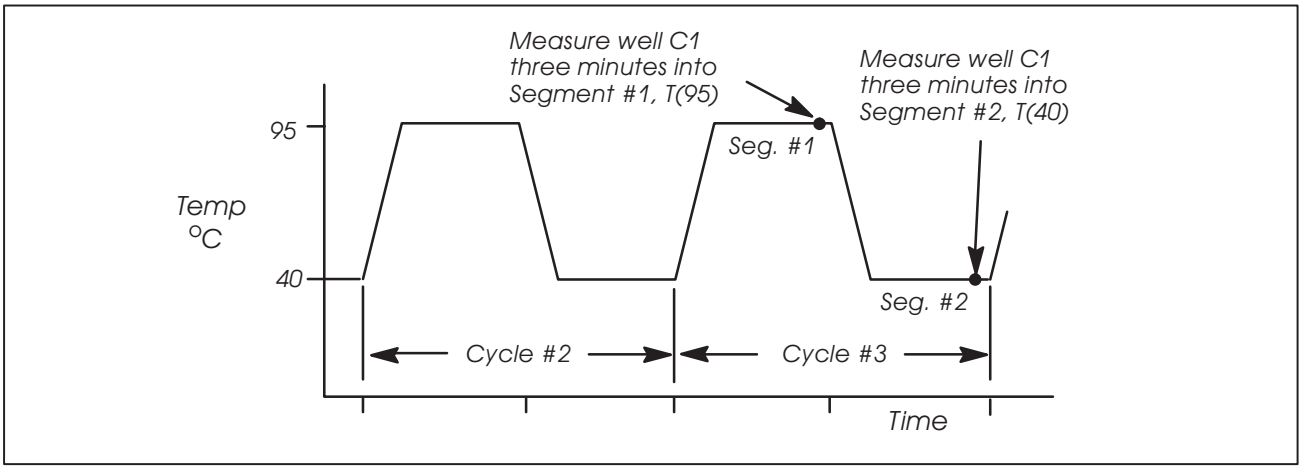

Figure 9.2: Temperature measurements in the temperature calibration verification test.

AFFIX THE CALIBRATION LABEL HERE

Figure 9.3: Calibration label.

NOTE: If you have more than one LCx Thermal Cycler in your laboratory, make sure that the serial number on the calibration label matches the serial number on the instrument you are testing.

The *offset* is the number of degrees Celsius that the temperature of well C1 differed from the average temperature of the block when the instrument was calibrated at the factory.

8. Use the following formula to calculate the average block temperature at the 95°C hold. Refer to the calibration label in Figure 9.3 for the High Offset value.

   Block Average at 95°C = T(95) – High Offset

   For example:

   C1 temp [T(95)] = 95.2°C

   High offset (on calibration label) = –0.1

   Use the following formula for computing the block average at 95°C:

   Block Average at 95°C = 95.2 – (–0.1)
   = 95.3°C

   - If the block average is more than 1°C above or below the programmed target temperature, the LCx Thermal Cycler needs to be recalibrated. Refer to **Section 6:** ***Calibration Procedures*****.**

     In this example, since 95.3°C is not more than 1°C above your programmed target temperature, your instrument would not need to be recalibrated.

9. Use the following formula to calculate the average block temperature at the 40°C hold. Refer to the calibration label in Figure 9.3 for the Low Offset value.

   Block Average at 40°C = T(40) – Low Offset

   For example:

   C1 temp [T(40)] = 39.9°C

   Low Offset (on your calibration label) = +0.1

   Block Average at 40°C = 39.9 – (+0.1)
   = 39.8°C

   - If the block average is more than 1°C above or below the programmed target temperature, the LCx Thermal Cycler needs to be recalibrated. Refer to **Section 6:** ***Calibration Procedures.***

     In this example, since 39.8°C is not more than 1°C above your programmed target temperature, your instrument would not need to be recalibrated.

10. Remove the probe from the sample block. Turn off the Temperature Verification System.
11. Press **[STOP]** to abort the Step-Cycle file.

This completes the test. Your calibration has now been verified.

If the calculated T_{avg} at 40°C or T_{avg} at 95°C differs from the target temperature by more than 1°C, perform a Temperature Calibration as described in **Section 6:** ***Calibration Procedures.***

Yearly Maintenance

Temperature Uniformity Test

Use this procedure to test the temperature uniformity of the Thermal Cycler sample block.

Equipment

You will need the following equipment to perform this procedure:

Provided

- Temperature Verification System, which includes:
  - Digital Thermometer (9V battery installed) with probe
  - Temperature Verification System Operators Manual

Required (but not provided)

- A one-pound weight to keep the sample block cover closed (minimum 1 lb. (.45 Kg))

Procedure

Perform the test as follows:

1. Turn on the instrument and let it warm up for 15 minutes.
2. Create a two-temperature Step-Cycle file with the following parameters:

Table 9.5: Step-Cycle File Parameters

Segment	Temperature	Time (in minutes)
1	95°C	1:00
2	40°C	1:00
3	0°C	0:00
Auto Segment Extension: off Cycle Count = 99 Link to Shut-off (0)		

3. Place the probe into the sample block well A1 (see Figure 9.5).
4. Press down firmly on the probe, close the sample block cover, and place the one-pound weight on the cover. Do not use any force when you close the cover.
5. Turn on the Temperature Verification System.
6. Run the two-temperature Step-Cycle file that you set up in Step 2.
7. At cycle 96 or lower, measure the temperature of well A1 when 0:00 seconds remain in both Segments #1 and #2. Record the Segment #1 temperature as T(95). Record the Segment #2 temperature as T(40) (see Figure 9.4).

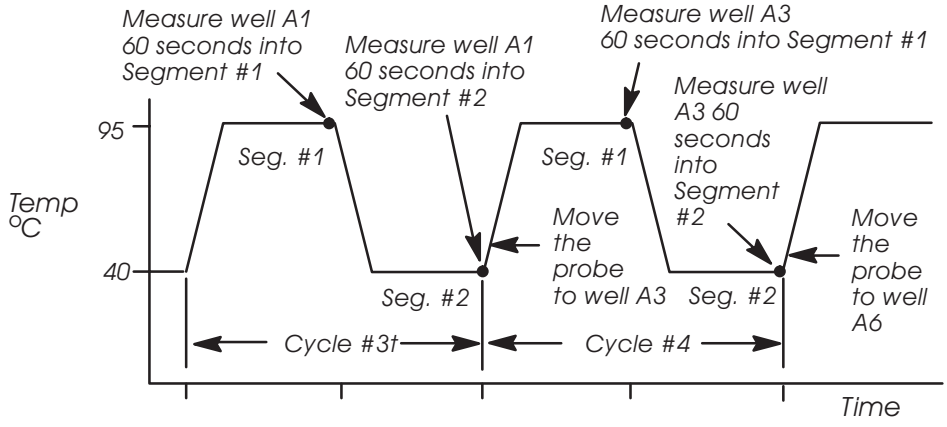

Figure 9.4: Temperature measurements in the temperature uniformity test.

8. After you measure the second temperature of well A1, remove the weight, lift the block cover, and move the probe to well A3. Close the cover, replace the weight, and repeat the measurements of Segments #1 and #2.
9. Repeat these measurements on wells A6, A8, C1, C3, C6, C8, F1, F3, F6, and F8 (see Figure 9.5).

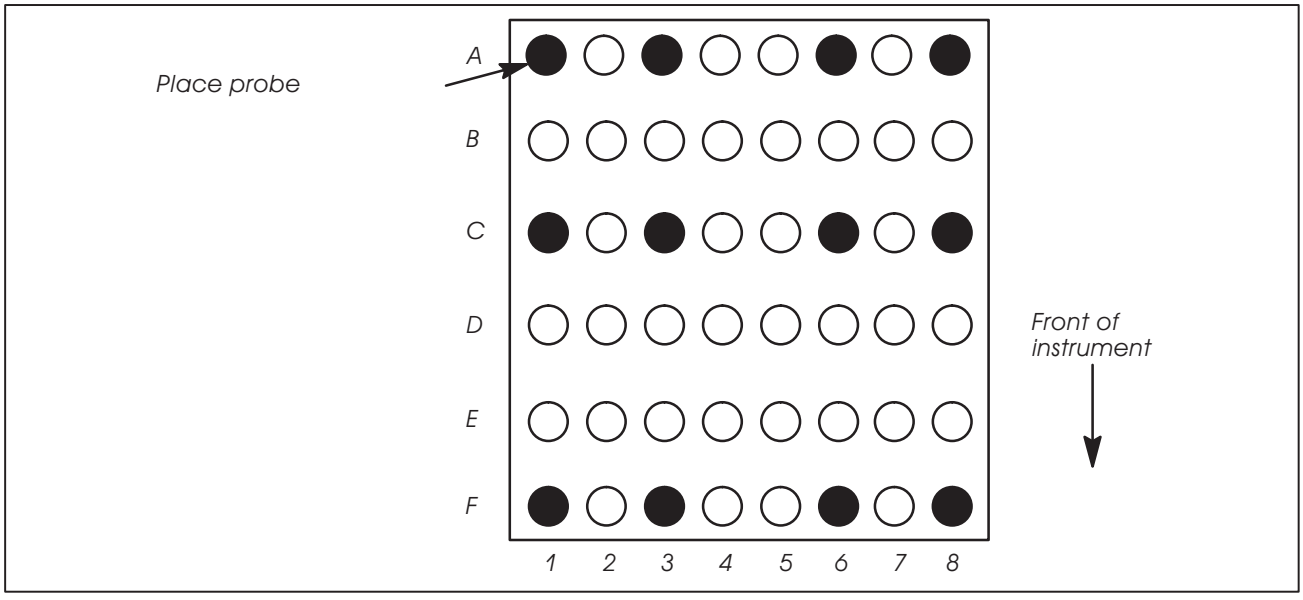

Figure 9.5:s Location of sample wells used in Uniformity Test.

10. For both the twelve Segment #1 measurements (95°C hold) and the twelve Segment #2 measurements (40°C hold), subtract the coldest temperature from the hottest temperature you have measured.
    - If the result is greater than 1°C, your instrument needs to be recalibrated. Refer to **Section 6:** ***Calibration Procedures.***
11. Compute the average of the twelve Segment #1 measurements (95°C hold). If the average is more than ±1°C of the setpoint (95°C), perform a temperature calibration verification test.
12. Compute the average of the twelve Segment #2 measurements (40°C hold). If the average is more than ±1°C of the setpoint (40°C), perform a temperature calibration verification test.
13. Press **[STOP]** to abort the Step-Cycle file.

Temperature Verification System

We recommend that the Temperature Verification System be recalibrated once a year.

Refer to the operator's manual provided with the Temperature Verification System for calibration instructions.

WARNING: Do not try to recalibrate or perform any service on the digital thermometer. The only user-serviceable component in the unit is the battery.

WARNING: Potential Biohazard. Decontaminate the Temperature Verification System prior to shipping. Ship the Temperature Verification System in the case provided.

As Required Maintenance

NOTE: Chlorine solutions may pit equipment and metal. Remove chlorine with sufficient amounts or repeated applications of 70% ethanol until all chlorine bleach residues are no longer visible.

Sample Block Decontamination

WARNING: Disconnect power to the thermal cycler before performing the decontamination procedure.

WARNING: Potential Biohazard. The LCx Thermal Cycler should be cleaned and thoroughly decontaminated prior to shipment or transfer from one laboratory to another.

WARNING: The LCx Thermal Cycler should be cleaned and thoroughly decontaminated in the case of a spill or accidental opening of an amplification vial during thermal cycling.

1. Fill each sample block well to approximately half of its capacity with 1.0% sodium hypochlorite solution (20% chlorine bleach).
2. Using a cotton swab, swirl the bleach solution in each well to clean the walls.
3. Using a pipettor, aspirate the bleach from each well.
4. Dispense distilled water in each well approximately to full capacity. Swirl water with cotton swab to wash all walls.
5. Wipe the surface of the sample block with a tissue moistened with 20% bleach.
6. Wipe the bleach-treated surface with a tissue moistened with distilled water.
7. Aspirate the water from each sample well.
8. Dispense 70% ethanol in each sample well.
9. Aspirate the ethanol from each sample well.
10. Wipe the surface of the sample block with a tissue moistened with 70% ethanol solution. Use sufficient amounts of ethanol or repeated applications of ethanol until chlorine residue is no longer visible.
11. Allow the sample block to dry.
12. Check for particulate matter in each well. If noticed, remove with a cotton swab.

Thermal Cycler Surfaces Decontamination

WARNING: Potential Biohazard. The LCx Thermal Cycler should be cleaned and thoroughly decontaminated prior to shipment or transfer from one laboratory to another.

WARNING: The LCx Thermal Cycler should be cleaned and thoroughly decontaminated in the case of a spill or accidental opening of an amplification vial during thermal cycling.

For Thermal Cycler Surfaces Decontamination, refer to ***Monthly Maintenance*** in this section.

Accidental Opening of an Amplification Vial

If an amplification vial accidentally opens during thermal cycling:

1. After thermal cycling is completed, remove the vial, close it and dispose of it in a biohazardous waste container. Remove and dispose of gloves worn during this step in a biohazardous waste container.
2. Be sure to put on a clean pair of gloves before you remove the remaining vials from the sample block. Refer to **Section 5:** ***Operating Instructions,*** **Subsection:** ***Unloading Samples.***
3. When all samples have been removed from the sample block and the sample block temperature is less than 37°C, decontaminate the sample block and sample block cover. For Sample Block Decontamination and Thermal Cycler Surfaces Decontamination, refer to ***Monthly Maintenance*** in this section.

Tube Racks

Perform the following procedure before moving tube racks from Area 2:

1. Soak racks in a 1.0% sodium hypochlorite solution (20% chlorine bleach) for a minimum of 10 minutes.
2. Rinse thoroughly with water.

Condensation Removal

You may remove condensation from the sample block in two ways:

- Use tissues and cotton swabs to remove accumulated condensation from the sample block and sample wells.
- For best results, run a 99°C soak file for 10 to 15 minutes without samples to thoroughly dry the sample block.

Temperature Verification System Battery Installation

The Temperature Verification System is powered by a 9V battery, which has been installed at the factory.

Refer to the operator's manual provided with the Temperature Verification System for battery replacement instructions.

NOTES

Troubleshooting and Diagnostics
Section Table of Contents

Overview

Diagnostics

Troubleshooting

NOTES

Overview

This section describes system diagnostics and troubleshooting procedures for the LCx Thermal Cycler.

LCx Customer Support Center (CSC)

Customer support is provided to answer any questions you may have about the LCx Thermal Cycler and to help you with any observed problems presented in this section. Contact your Customer Support Representative at:

United States: 1-800-527-1869

Canada English: 1–800–387–8378
Canada French: 1–800–456–2675

Other Countries: Call your local Customer Service Representative.

NOTES

Diagnostics

Diagnostic Files

The Diagnostic file contains six diagnostic tests:

- Display/Keypad Test, Test #1
- Delete User Files, Test #2
- Heater Test, Test #3
- Chiller Test, Test #4
- Overshoot Test, Test #5
- Undershoot Test, Test #6

Accessing Diagnostic Files

You can only access the Diagnostic files from the first display in a file.

1. To access the Diagnostic files, press:

   [FILE]
   [YES]
   [NO]
   [ENTER]

2. Access the specific test you wish to run by pressing:

   Test Number
   [ENTER]

Test Procedures

Display/Keypad Test (Test #1)

The first part of this procedure tests the ability of the display to illuminate each dot or character; the second part tests the operation of the keypad. If either part of the test fails, contact LCx CSC.

Table 10.1: Display/Keypad Test

Display	Keystrokes	Task
The first display of any file	**FILE**, **YES**	Access Configuration and Diagnostic option
`Select Function` `CONFIG-DIAGNOSTIC`	**NO**, **ENTER**	Select Diagnostics
`Diagnostic Tests` `Enter test #  (1-6)`	**1**, **ENTER**	Access Display/Keypad Test
`Display/Keypad Test`		Cursor moves through all display positions
`Enter key`	each key	Display each key name
	STOP	Display **STOP**
`Enter key` `STOP`	**STOP**	Exit the Display/Keypad Test
`Diagnostic Tests` `Enter test# (1–6)`	Test Number, **ENTER** or **STOP**	Run another Diagnostic test or Exit Diagnostic File

Delete User Files (Test #2)

All Files

This procedure allows you to delete ALL files that are stored in the instrument's memory (File Number 5–99).

Table 10.2: Delete User Files Test

Display	Keystrokes	Task
The first display of any file	**FILE**, **YES**	Access Configuration and Diagnostic option
`Select Function` `CONFIG-DIAGNOSTIC`	**NO**, **ENTER**	Select Diagnostics
`Diagnostic Tests` `Enter test #  (1-6)`	**2**, **ENTER**	Access Delete User Files Test
`Delete User Files?` `Press YES or NO`	**YES**	Delete all user files
`Are you sure?` `Press YES or NO`	**YES**	Confirm and initiate user file deletion
	STOP	Exit Delete User Files Test
`Diagnostic Tests` `Enter test# (1–6)`	Test Number, **ENTER** or **STOP**	Run another Diagnostic test or Exit Diagnostic File

NOTE: You cannot delete an individual file with this procedure.

Individual Files

To delete an individual user file:

Press **[FILE]**
File Number
[ENTER]
[FILE]
[CLEAR]

Heater Test (Test #3)

The Heater Test measures the maximum heating rate and the heating time in seconds required for the first 15°C of temperature change. This information is displayed when the test has been completed.

Table 10.3: Heater Test Procedure

Display	Keystrokes	Task
The first display of any file	**FILE**, **YES**	Access Configuration and Diagnostic option
`Select Function` `CONFIG-DIAGNOSTIC`	**NO**, **ENTER**	Select Diagnostics
`Diagnostic Tests` `Enter test # (1-6)`	**3**, **ENTER**	Run Heater Test
`Heater Test Blk= xxC` `going to 35C...`		Block cooling
`Heater Test Blk= 35C` `wait 1 min... :xx`		Block temperature reaches 35°C
`Heater Test Blk= xxC` `heating...`		Block temperature warming

Heating Rate ↓
`Heat Rate= 0.97°/sec`
`Time= 17s`
↑ *Heating Time*
		Block temperature displays

`Heat Rate= 0.97°/sec` `Time= 17s`	**STOP**	Exit Heater Test
`Diagnostic Tests` `Enter test # (1-6)`	Test Number, **ENTER** or **STOP**	Run another Diagnostic Test or Exit Diagnostic File

Compare your results with Table 10.4. If any of the numbers displayed at the end of the test are outside the normal range, contact LCx CSC.

Table 10.4: Heater Test Results by Line Voltage

			Your heater rate should be ≥:	Your heating time should be ≤:
100 VAC	240 VAC	120 VAC	0.67 °/second	30 seconds

Chiller Test (Test #4)

The Chiller Test cools the block and measures the maximum cooling rate of the instrument. This test should be run only after the instrument has been idle for at least 30 minutes to allow the coolant to reach operating temperature.

Table 10.5: Chiller Test Procedure

Display	Keystrokes	Task
First display of any file	**FILE, YES**	Access the Configuration-Diagnostic option
`Select Function` `CONFIG-DIAGNOSTIC`	**NO, ENTER**	Access Diagnostic File
`Diagnostic Tests` `Enter test# (1-6)`	**4, ENTER**	Run the Chiller test
`Chiller Test Blk=xxC` `going to 85C`		Block warming
`Chiller Test Blk=85C` `wait 1 min... :xx`		Block temperature reaches 85°C
`Chiller Test Blk=xxC` `cooling...`		Block temperature holds at 85°C for 1 minute
`Cool Rate=1.18° /sec`		Block temperature displays
	STOP	Exit Chiller test
`Diagnostic Tests` `Enter test# (1-6)`	Test Number, **ENTER** or **STOP**	Run another Diagnostic test or Exit Diagnostic File

The cooling rate should be between 0.85°/second and 1.90°/second.

Overshoot Test (Test #5)

This test measures how much the block temperature exceeds a specified temperature as it ramps up from 37°C to 94°C.

Table 10.6: Overshoot Test

Display	Keystrokes	Task
First display of any file	**FILE, YES**	Access the Configuration-Diagnostic option
`Select Function` `CONFIG-DIAGNOSTIC`	**NO, ENTER**	Select Diagnostics
`Diagnostic Tests` `Enter test# (1-6)`	**5, ENTER**	Access Overshoot Test

current block temp.
`Overshoot Blk= xxC`
`going to 37C...`
target temp.
		Temperature going to 37°C

`Overshoot Blk= 37C`
`wait 1 min... :xx`
counter
		Block temperature holds at 37°C for one minute

`Overshoot Blk= xxC` `going to 94C...`		Temperature going to 94°C
`Overshoot Blk= 94C` `going to 94C...`		Block temperature holds at 94°C for 15 seconds
`Overshoot = 0.1C`	**STOP**	Exit Overshoot Test
`Diagnostic Tests` `Enter test# (1-6)`	Test Number, **ENTER** or **STOP**	Run another Diagnostic test or Exit Diagnostic File

If the overshoot is greater than 0.5°C, contact the LCx CSC.

Undershoot Test (Test #6)

This test measures the failure of the block to reach a specified temperature when it moves down from 94°C to 55°C.

Table 10.7: Undershoot Test

Display	Keystrokes	Task
First display of any file	**FILE, YES**	Access the Configuration-Diagnostic option
`Select Function` `CONFIG-DIAGNOSTIC`	**NO, ENTER**	Select Diagnostics
`Diagnostic Tests` `Enter test# (1-6)`	**6, ENTER**	Access Undershoot Test

current block temp. ↓
`Undershoot Blk= xxC`
`going to 94C...`
↑ *target temp.*
		Temperature going to 94°C

`Undershoot Blk= 94C`
`wait 1 min... :xx`
counter ↑
		Block temperature holds at 94°C for one minute

`Undershoot Blk= xxC` `going to 55C...`		Temperature going to 55°C
`Undershoot Blk= 55C` `going to 55C...`		Block temperature holds at 55°C for 15 seconds
`Undershoot = 0.6C`	**STOP**	Exit Undershoot Test
`Diagnostic Tests` `Enter test# (1-6)`	Test Number, **ENTER** or **STOP**	Run another Diagnostic test or Exit Diagnostic File

If the downward overshoot is greater than 2°C, call LCx CSC.

Troubleshooting

Troubleshooting Procedures

The following table lists basic instrument problems you may have, the probable causes of these problems, and what you should do to correct them. If any of these problems cannot be resolved using the corrective action provided, call LCx CSC.

Problem	Probable Cause	Corrective Action
The power switch is on but there is no response.	The power cable is loose or not plugged in.	Plug the power cable in properly.
There is no display on the screen and no noise from the motor or fan.	The main fuse is blown.	Replace the main fuse (FI). Call LCx CSC.
Power is on but the screen is blank. Or, when you press a key, the display does not show the appropriate response or the screen is blank.	The logic/power supply fuse may be blown, or there may be a controller problem.	Replace the fuse or call Abbott CSC.
The displayed block temperature appears to be inaccurate.	Calibration may be required.	Perform a temperature calibration verification using the Temperature Verification System. Refer to **Section 9: *Service and Maintenance,* Subsection: *Monthly Maintenance.*** Recalibrate as necessary.
The heating or cooling is too slow.	There is a possible controller or mechanical malfunction.	Run Diagnostic Test #3 (Heater Test) and record the heating rate. Run a 4°C Soak file and see if the target temperature is achieved in 15 minutes. Call LCx CSC if either test fails.
An error message is displayed when you turn on the instrument.	One of the main systems of the instrument has failed.	Call LCx CSC.
Step-Cycle File #4 displays during a Thermo-Cycle or Soak File run.	Instrument power has been interrupted.	Remove and dispose of samples according to procedure in **Section 5: *Operating Instructions,* Subsection: *Unloading Samples.*** If problem recurs, call LCx CSC.

Power Interruption

If power is interrupted by a power failure, power surge, etc. and the instrument turns off:

- While you are editing a file, you will lose that file and will have to re-edit it.
- After you have just stored a file, you will not lose that file.
- While you are in the middle of a run, you will lose that run. When power is restored, you can run the file again.

⚠ **CAUTION:** If power is interrupted at any time during a thermal cycler run, the run is invalid. Do not continue to process these samples. Make sure the amplification vial caps are tightly closed. Remove carefully to a biohazard bag. Seal the bag and dispose of according to waste disposal procedures in **Section 8:** ***Hazards,*** **Subsection:** ***Biosafety.***

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Revision Status

Document Control Number(s)	Revision Date	Section(s) Revised	Pages Revised And Added
Originally Issued	4/95	Not Applicable	Not Applicable
47287-102	6/96	All Sections	All Pages

NOTES

Revision Log

Instructions: Use this log to provide a permanent record to verify that a revised section(s) has been added to this manual.

1. Record the document control number in the first column. You will find the number in the footer. Make an entry for each section you receive and place in the manual.
2. Record the revision date, also found in the footer in the second column.
3. Write your initials in the fourth column to verify that you have placed the revised pages in the manual.
4. Record the date that you added the revised section to the manual in the fifth column.

Document Control Number(s)	Revision Date	Software Version (if applicable)	Revision Incorporated by	Date Incorporated

NOTES

Glossary

active segment — Part of the thermal amplification procedure in which some process occurs.

amplification — Process of copying a target DNA sequence.

amplification parameters — Time and temperature values that the LCx Thermal Cycler uses to run an amplification assay. The values may be different for each assay.

amplification product — Product of the thermal cycling process.

amplification vial — Container in which amplification reaction takes place. Provided by Abbott with the LCx diagnostic kits.

amplified specimen — Specimen that has undergone thermal amplification.

anneal — To (re)establish base pairing between complementary strands of DNA.

block temperature — Temperature of the LCx Thermal Cycler sample block.

block temperature overshoot — An amount by which the temperature of the sample block in the thermal cycler exceeds the target temperature after it has been heated.

block temperature undershoot — An amount by which the temperature of the sample block in the thermal cycler falls short of achieving a target temperature as the block cools.

calibration label — Label indicating the serial number of the instrument and the results of the temperature calibration verification test.

calibrator — An analyte containing standard, used to calculate the LCx assay cutoff value.

Chiller test — Test for measuring the maximum cooling rate of the thermal cycler.

configuration parameter — Thermal cycler parameters including the pause time-out limit and printer mode which are set at installation.

Cooling test — Test that verifies the efficiency of the cooling system of the thermal cycler.

count-down clock	A digital display which, during a run, counts down from the programmed time to zero marking the conclusion of the thermal cycler run.
cycle	A series of time and temperature settings or segments with a clear beginning and endpoint which can be repeated.
cycle time reproducibility	Test that verifies incubation times and temperatures.
cycle count	The number of times a cycle is repeated.
default value	A value in a program that has been preset in the software.
delay time	Length of time the block is under thermal control; including both transition and incubation time.
denature	The process of breaking down the complementary base pairing of DNA by heating or chemical means.
Diagnostic File	System file containing tests used to confirm the proper functioning of the instrument.
Display/keypad test	Test used to check the operation of the keypad and of each display character in the thermal cycler.
factory set	Process performed at the factory or by qualified service personnel to reset an instrument to default system values.
file directory	A list of available files within the thermal cycler software.
gap-filling	A reaction by which the gap between two adjacent probes, that hybridize to the target DNA, is filled with deoxynucleotides.
Heater test	Test for measuring the maximum heating rate and time for the first 15°C of temperature change in the thermal cycler.
heating rate	Rate in degrees per second at which the heater achieves a target temperature in the thermal cycler.
hold time	Period of time target temperature is maintained in the thermal cycler.

hybridization	The pairing of two single-stranded DNA molecules.
keypad	Alphanumeric data entry panel built into the thermal cycler.
ligation	Covalent attachment of two adjacent DNA sequences by the enzyme ligase.
MEIA	Abbreviation for Microparticle Enzyme Immunoassay; technology used in the LCx Analyzer to detect amplification product.
nuclease	Enzymes that hydrolyze nucleic acid.
nucleic acid	A polynucleotide found especially in cell nuclei.
nucleic acid probe	A synthesized sequence of nucleic acid that is complementary to a portion of the target nucleic acid being detected in the LCx Analyzer.
nucleotide	A single base of nucleic acid composed of a sugar phosphate group and a base.
offset value	Number of degrees difference between the temperature of one well and the average temperature of the block.
Overshoot test	Test used to verify sample block is not heating to temperatures in excess of target temperature.
pause time-out limit	The point at which a run will automatically be aborted after STOP has been pressed.
polymerization	The process of forming a compound.
protease	An enzyme that catalyzes the hydrolytic breakdown of proteins.
ramp rate	Ratio of temperature to time for heating and cooling the sample block.
ramp time	Length of time required to transition from one temperature to another in the sample block of the thermal cycler.
ramp time reproducibility	Reproducibility of programmed ramp times in the thermal cycler.

run-time display	Thermal cycler display showing target temperature and elapsed time.
sample block	Programmable heating and cooling block in the thermal cycler into which samples are placed.
sample well	A place in the sample block of the thermal cycler into which specimens are placed.
segment	A part of the Step-Cycle or Thermo-Cycle file that incorporates target temperatures and hold times.
setpoint	Target value of an automatically controlled variable.
Soak File	A file in the thermal cycler which maintains a single temperature within the sample block until a run is aborted.
sodium hypochlorite	A component of chlorine bleach which is used as a disinfectant.
Step-Cycle File	A file in the thermal cycler which contains programmed thermal plateaus for thermal amplification.
strand	A single long chain of connected nucleotides.
target DNA	A sequence of interest within the genome of the bacteria for which the test is designed.
target temperature	Programmed temperature that signals the end of a process.
temperature calibration	Procedure that allows the user to calibrate the temperature control of the LCx Thermal Cycler.
temperature calibration verification test	Test to verify that the temperature of the LCx Thermal Cycler remains in calibration.
temperature check	Procedure that allows the user to check the temperature control of the LCx Thermal Cycler.
Temperature Uniformity test	Test for uniformity of the temperature within the sample block of the thermal cycler.
terminating segment	The final segment in a thermal cycler file in which time and temperature are set to zero. This segment informs the thermal cycler that it has reached the end of a cycle.

thermal amplification file	A Thermo-Cycle or Step-Cycle file in the LCx Thermal Cycler.
thermal control parameter	Time and temperature settings.
thermal plateau	Even-numbered segments in a Thermo-Cycle file which contain target temperatures and hold times.
thermal transition	A change between two constant temperatures.
Thermo-Cycle File	A file in the thermal cycler which contains programmed thermal transitions and thermal plateaus.
Time Delay File	A file in the thermal cycler which holds a single temperature for a specified period of time as programmed.
transition time	Time required to meet a target temperature in the thermal cycler.
Undershoot test	Test that verifies that the sample block in the thermal cycler does not fail to reach target temperature as it cools.
user file	File created by editing the parameters of a default file in the thermal cycler.

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