Thermal Cycler Temperature Verification System

For GeneAmp® PCR Systems with a 0.2-mL Sample Block

User Guide

Applied Biosystems

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Preface

How to Use This Guide

Purpose of This Guide

The *Applied Biosystems Thermal Cycler Temperature Verification System User Guide* provides information for using the Thermal Cycler Temperature Verification System with GeneAmp® PCR Systems with a 0.2-mL Sample Block. It describes the specific tests for the various thermal cyclers with which it is used.

Audience

This guide is intended for novice and experienced GeneAmp® PCR System users.

Text Conventions

This guide uses the following conventions:

- **Bold** indicates user action. For example:

  Type **0**, then press **Enter** for each of the remaining fields.
- *Italic* text indicates new or important words and is also used for emphasis. For example:

  Before analyzing, *always* prepare fresh matrix.
- A right arrow bracket (>) separates successive commands you select from a drop-down or shortcut menu. For example:

  Select **File > Open > Spot Set**.

  Right-click the sample row, then select **View Filter > View All Runs**.

User Attention Words

Two user attention words appear in Applied Biosystems user documentation. Each word implies a particular level of observation or action as described below:

Note: Provides information that may be of interest or help but is not critical to the use of the product.

IMPORTANT! Provides information that is necessary for proper instrument operation, accurate chemistry kit use, or safe use of a chemical.

Examples of the user attention words appear below:

Note: The size of the column affects the run time.

Note: The Calibrate function is also available in the Control Console.

IMPORTANT! To verify your client connection to the database, you need a valid Oracle user ID and password.

IMPORTANT! You must create a separate Sample Entry Spreadsheet for each 96-well microtiter plate.

Safety Alert Words

Safety alert words also appear in user documentation. For more information, see "Safety Alert Words" on page viii.

Send Us Your Comments

Send Us Your Comments

Applied Biosystems welcomes your comments and suggestions for improving its user documents. You can e-mail your comments to:

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For the latest services and support information for all locations, go to **http://www.appliedbiosystems.com**, then click the link for **Services and Support**.

At the Services and Support page, you can:

- Search through frequently asked questions (FAQs)
- Submit a question directly to Technical Support
- Order Applied Biosystems user documents, MSDSs, certificates of analysis, and other related documents
- Download PDF documents
- Obtain information about customer training
- Download software updates and patches

In addition, the Services and Support page provides access to worldwide telephone and fax numbers to contact Applied Biosystems Technical Support and Sales facilities.

Safety and EMC Compliance Information

This section includes the following topics:

Safety Conventions Used in This Document

Safety Alert Words

Four safety alert words appear in Applied Biosystems user documentation at points in the document where you need to be aware of relevant hazards. Each alert word–**IMPORTANT, CAUTION, WARNING, DANGER**–implies a particular level of observation or action, as defined below:

Definitions

IMPORTANT! – Indicates information that is necessary for proper instrument operation, accurate chemistry kit use, or safe use of a chemical.

– Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

– Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.

– Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury. This signal word is to be limited to the most extreme situations.

Except for IMPORTANTs, each safety alert word in an Applied Biosystems document appears with an open triangle figure that contains a hazard symbol. *These hazard symbols are identical to the hazard icons that are affixed to Applied Biosystems instruments* (see "Safety Symbols" on page ix).

Examples

The following examples show the use of safety alert words:

IMPORTANT! You must create a separate Sample Entry Spreadsheet for each 96-well microtiter plate.

The lamp is extremely hot. Do not touch the lamp until it has cooled to room temperature.

CHEMICAL HAZARD. **Formamide**. Exposure causes eye, skin, and respiratory tract irritation. It is a possible developmental and birth defect hazard. Read the MSDS, and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves.

ELECTRICAL HAZARD. Failure to ground the instrument properly can lead to an electrical shock. Ground the instrument according to the provided instructions.

Symbols on Instruments

Electrical Symbols on Instruments

The following table describes the electrical symbols that may be displayed on Applied Biosystems instruments.

Symbol	Description
	Indicates the **On** position of the main power switch.
	Indicates the **Off** position of the main power switch.
	Indicates the **On/Off** position of a push-push main power switch.
	Indicates a terminal that may be connected to the signal ground reference of another instrument. This is not a protected ground terminal.
	Indicates a protective grounding terminal that must be connected to earth ground before any other electrical connections are made to the instrument.
	Indicates a terminal that can receive or supply alternating current or voltage.
	Indicates a terminal that can receive or supply alternating or direct current or voltage.

Safety Symbols

The following table describes the safety *s*ymbols that may be displayed on Applied Biosystems instruments. Each symbol may appear by itself or in combination with text that explains the relevant hazard (see "Safety Labels on Instruments" on page x). These safety symbols may also appear next to DANGERS, WARNINGS, and CAUTIONS that occur in the text of this and other product-support documents.

Symbol	Description
	Indicates that you should consult the manual for further information and to proceed with appropriate caution.
	Indicates the presence of an electrical shock hazard and to proceed with appropriate caution.
	Indicates the presence of a hot surface or other high-temperature hazard and to proceed with appropriate caution.

Symbol	Description
	Indicates the presence of a laser inside the instrument and to proceed with appropriate caution.
	Indicates the presence of moving parts and to proceed with appropriate caution.

Safety Labels on Instruments

The following CAUTION, WARNING, and DANGER statements may be displayed on Applied Biosystems instruments in combination with the safety symbols described in the preceding section.

English	Francais
CAUTION Hazardous chemicals. Read the Material Safety Data Sheets (MSDSs) before handling.	**ATTENTION** Produits chimiques dangeureux. Lire les fiches techniques de sûreté de matériels avant la manipulation des produits.
CAUTION Hazardous waste. Read the waste profile (if any) in the site preparation guide for this instrument before handling or disposal.	**ATTENTION** Déchets dangereux. Lire les renseignements sur les déchets avant de les manipuler ou de les éliminer.
CAUTION Hazardous waste. Refer to MSDS(s) and local regulations for handling and disposal.	**ATTENTION** Déchets dangereux. Lire les fiches techniques de sûreté de matériels et la régulation locale associées à la manipulation et l'élimination des déchets.
WARNING Hot lamp.	**AVERTISSEMENT** Lampe brûlante.
WARNING Hot. Replace lamp with an Applied Biosystems lamp.	**AVERTISSEMENT** Composants brûlants. Remplacer la lampe par une lampe Applied Biosystems.
CAUTION Hot surface.	**ATTENTION** Surface brûlante.
DANGER High voltage.	**DANGER** Haute tension.
WARNING To reduce the chance of electrical shock, do not remove covers that require tool access. No user-serviceable parts are inside. Refer servicing to Applied Biosystems qualified service personnel.	**AVERTISSEMENT** Pour éviter les risques d'électrocution, ne pas retirer les capots dont l'ouverture nécessite l'utilisation d'outils. L'instrument ne contient aucune pièce réparable par l'utilisateur. Toute intervention doit être effectuée par le personnel de service qualifié de Applied Biosystems.
CAUTION Moving parts.	**ATTENTION** Parties mobiles.

General Instrument Safety

WARNING **PHYSICAL INJURY HAZARD.** Use this product only as specified in this document. Using this instrument in a manner not specified by Applied Biosystems may result in personal injury or damage to the instrument.

Moving and Lifting the Instrument

CAUTION **PHYSICAL INJURY HAZARD.** The instrument is to be moved and positioned only by the personnel or vendor specified in the applicable site preparation guide. If you decide to lift or move the instrument after it has been installed, do not attempt to lift or move the instrument without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques. Improper lifting can cause painful and permanent back injury. Depending on the weight, moving or lifting an instrument may require two or more persons.

Moving and Lifting Stand-Alone Computers and Monitors

WARNING Do not attempt to lift or move the computer or the monitor without the assistance of others. Depending on the weight of the computer and/or the monitor, moving them may require two or more people.

Things to consider before lifting the computer and/or the monitor:

- Make sure that you have a secure, comfortable grip on the computer or the monitor when lifting.
- Make sure that the path from where the object is to where it is being moved is clear of obstructions.
- Do not lift an object and twist your torso at the same time.
- Keep your spine in a good neutral position while lifting with your legs.
- Participants should coordinate lift and move intentions with each other before lifting and carrying.
- Instead of lifting the object from the packing box, carefully tilt the box on its side and hold it stationary while someone slides the contents out of the box.

Operating the Instrument

Ensure that anyone who operates the instrument has:

- Received instructions in both general safety practices for laboratories and specific safety practices for the instrument.
- Read and understood all applicable Material Safety Data Sheets (MSDSs). See "About MSDSs" on page xii.

Cleaning or Decontaminating the Instrument

CAUTION Before using a cleaning or decontamination method other than those recommended by the manufacturer, verify with the manufacturer that the proposed method will not damage the equipment.

Chemical Safety

Chemical Hazard Warning

WARNING **CHEMICAL HAZARD.** Before handling any chemicals, refer to the Material Safety Data Sheet (MSDS) provided by the manufacturer, and observe all relevant precautions.

WARNING **CHEMICAL HAZARD.** All chemicals in the instrument, including liquid in the lines, are potentially hazardous. Always determine what chemicals have been used in the instrument before changing reagents or instrument components. Wear appropriate eyewear, protective clothing, and gloves when working on the instrument.

WARNING **CHEMICAL HAZARD.** Four-liter reagent and waste bottles can crack and leak. Each 4-liter bottle should be secured in a low-density polyethylene safety container with the cover fastened and the handles locked in the upright position. Wear appropriate eyewear, clothing, and gloves when handling reagent and waste bottles.

WARNING **CHEMICAL STORAGE HAZARD**. Never collect or store waste in a glass container because of the risk of breaking or shattering. Reagent and waste bottles can crack and leak. Each waste bottle should be secured in a low-density polyethylene safety container with the cover fastened and the handles locked in the upright position. Wear appropriate eyewear, clothing, and gloves when handling reagent and waste bottles.

About MSDSs

Chemical manufacturers supply current Material Safety Data Sheets (MSDSs) with shipments of hazardous chemicals to *new* customers. They also provide MSDSs with the first shipment of a hazardous chemical to a customer after an MSDS has been updated. MSDSs provide the safety information you need to store, handle, transport, and dispose of the chemicals safely.

Each time you receive a new MSDS packaged with a hazardous chemical, be sure to replace the appropriate MSDS in your files.

Obtaining MSDSs

You can obtain from Applied Biosystems the MSDS for any chemical supplied by Applied Biosystems. This service is free and available 24 hours a day.

To obtain MSDSs:

1. Go to **https://docs.appliedbiosystems.com/msdssearch.html**
2. In the Search field, type in the chemical name, part number, or other information that appears in the MSDS of interest. Select the language of your choice, then click **Search**.
3. Find the document of interest, right-click the document title, then select any of the following:
   - **Open** – To view the document
   - **Print Target** – To print the document
   - **Save Target As** – To download a PDF version of the document to a destination that you choose

4. To have a copy of a document sent by fax or e-mail, select **Fax** or **Email** to the left of the document title in the Search Results page, then click **RETRIEVE DOCUMENTS** at the end of the document list.
5. After you enter the required information, click **View/Deliver Selected Documents Now**.

Chemical Safety Guidelines

To minimize the hazards of chemicals:

- Read and understand the Material Safety Data Sheets (MSDS) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. (See "About MSDSs" on page xii.)
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing). For additional safety guidelines, consult the MSDS.
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with adequate ventilation (for example, fume hood). For additional safety guidelines, consult the MSDS.
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer's cleanup procedures as recommended on the MSDS.
- Comply with all local, state/provincial, or national laws and regulations related to chemical storage, handling, and disposal.

Electrical Safety

DANGER **ELECTRICAL SHOCK HAZARD.** Severe electrical shock can result from operating the Thermal Cycler Temperature Verification System without its instrument panels in place. Do not remove instrument panels. High-voltage contacts are exposed when instrument panels are removed from the instrument.

Fuses

DANGER **ELECTRICAL SHOCK HAZARD.** Improper fuses or high-voltage supply can damage the instrument wiring system and cause a fire. Before turning on the instrument, verify that the fuses are properly installed and that the instrument voltage matches the power supply in your laboratory.

WARNING **FIRE HAZARD.** For continued protection against the risk of fire, replace fuses only with fuses of the type and rating specified for the instrument.

Power

DANGER **ELECTRICAL HAZARD.** Grounding circuit continuity is vital for the safe operation of equipment. Never operate equipment with the grounding conductor disconnected.

DANGER **ELECTRICAL HAZARD.** Use properly configured and approved line cords for the voltage supply in your facility.

DANGER **ELECTRICAL HAZARD.** Plug the system into a properly grounded receptacle with adequate current capacity.

Overvoltage Rating

The Thermal Cycler Temperature Verification System system has an installation (overvoltage) category of II, and is classified as portable equipment

Physical Hazard Safety

Moving Parts

PHYSICAL INJURY HAZARD. Moving parts can crush and cut. Keep hands clear of moving parts while operating the instrument. Disconnect power before servicing the instrument.

PHYSICAL INJURY HAZARD. Do not operate the instrument without the arm shield in place. Keep hands out of the deck area when the instrument is spotting.

Solvents and Pressurized Fluids

PHYSICAL INJURY HAZARD. Always wear eye protection when working with solvents or any pressurized fluids.

PHYSICAL INJURY HAZARD. To avoid hazards associated with high-pressure fluids in polymeric tubing:

- Be aware that PEEK™ tubing is a polymeric material. Use caution when working with any polymer tubing that is under pressure.
- Always wear eye protection when in proximity to pressurized polymer tubing.
- Extinguish all nearby flames if you use flammable solvents.
- Do not use PEEK tubing that has been severely stressed or kinked.
- Do not use PEEK tubing with tetrahydrofuran or concentrated nitric and sulfuric acids.
- Be aware that methylene chloride and dimethyl sulfoxide cause PEEK tubing to swell and greatly reduce the rupture pressure of the tubing.
- Be aware that high solvent flow rates (~40 mL/min) may cause a static charge to build up on the surface of the tubing. Electrical sparks may result.

Safety and Electromagnetic Compatibility (EMC) Standards

This section provides information on:

- U.S. and Canadian Safety Standards
- Canadian EMC Standard
- European Safety and EMC Standards
- Australian EMC Standards

U.S. and Canadian Safety Standards

This instrument has been tested to and complies with standard UL 3101-1, “Safety Requirements for Electrical Equipment for Laboratory Use, Part 1: General Requirements.”

This instrument has been tested to and complies with standard CSA 1010.1, “Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements.”

Canadian EMC Standard

This instrument has been tested to and complies with ICES-001, Issue 3: Industrial, Scientific, and Medical Radio Frequency Generators.

European Safety and EMC Standards

CE

Safety

This instrument meets European requirements for safety (Low Voltage Directive 73/23/EEC). This instrument has been tested to and complies with standards EN 61010-1:2001, "Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General Requirements" and EN 61010-2-010, "Particular Requirements for Laboratory Equipment for the Heating of Materials."

EMC

The 9700, 9600, 2700, and 2400 instruments meet European requirements for emission and immunity (EMC Directive 89/336/EEC). These instruments have been tested to and comply with standard EN 61326 (Group 1, Class B for the 9700, 2700, and 2400 instruments) (Group 1, Class A for the 9600 instrument), "Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements."

Australian EMC Standards

This instrument has been tested to and complies with standard AS/NZS 2064, "Limits and Methods Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radio-frequency Equipment."

Introduction 1

This chapter covers:

About This Manual

This manual describes the Temperature Verification System and the tests for the thermal cyclers with which it is used:

- GeneAmp® PCR System 9700, 96-Well Sample Block Module
- GeneAmp® PCR System 2700
- GeneAmp® PCR System 9700, Dual 96-Well Sample Block Module
- GeneAmp® PCR System 9600
- GeneAmp® PCR System 2400

This manual contains a separate chapter for each instrument, except for the system 9700 and system 2700, which share the same instructions. Each instrument chapter provides step-by-step instructions for performing two different tests, which are described in "Temperature Verification Tests" on page 1-4.

This manual is included in the kit (the Temperature Verification System, P/N 4317939) and is shipped with the 0.2-mL Probe Kit (P/N 4317938), when the 0.2-mL Probe Assembly is purchased separately.

About the Temperature Verification System

Description

The Temperature Verification System is a kit consisting of a probe, a digital thermometer, frames to prevent ambient air from entering the sample block, light mineral oil, and cotton swabs. The system is used to verify temperatures of the sample block on your thermal cycler. The major components of the system are shown in Figure 1-1 on page 1-3.

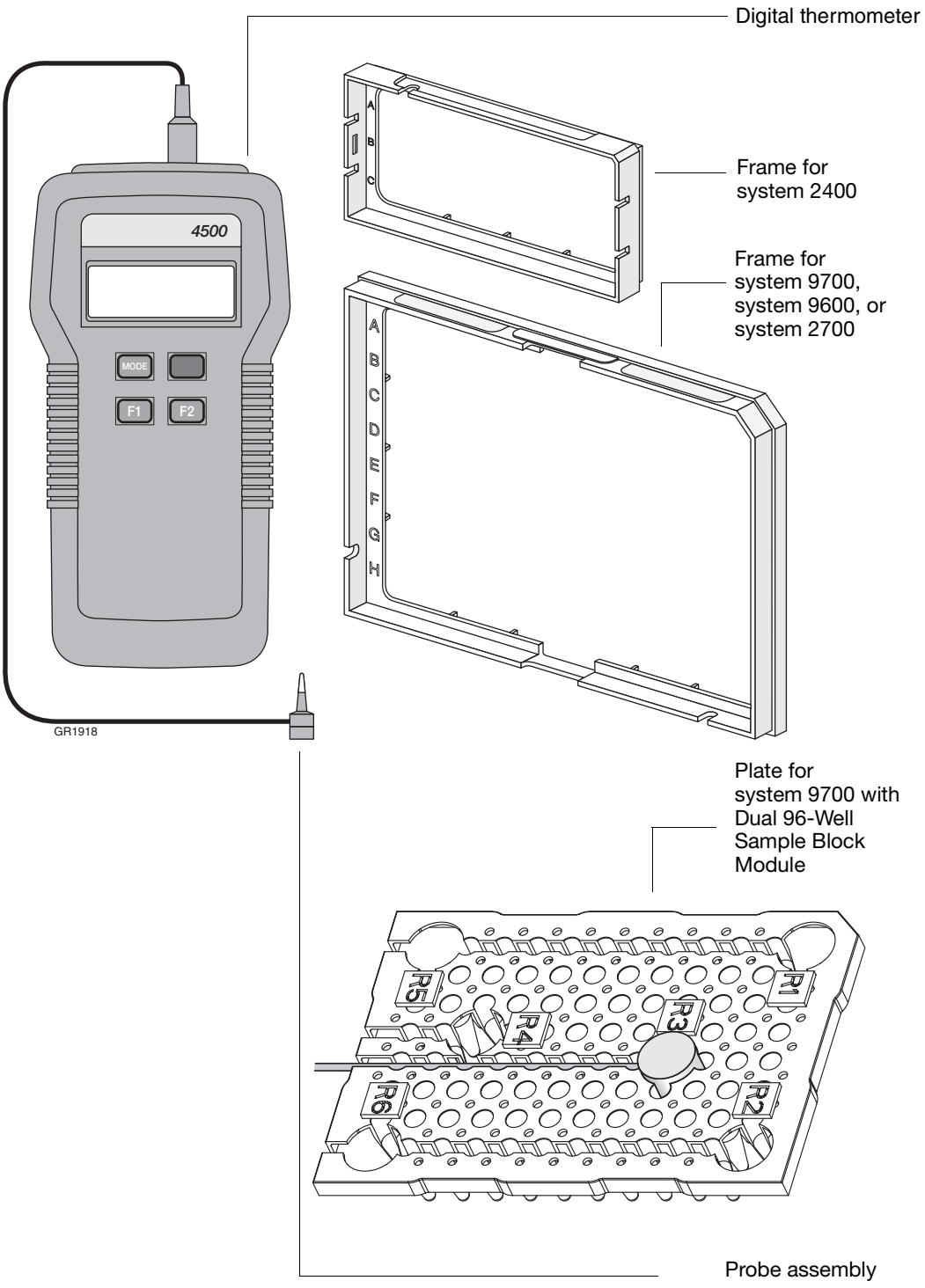


Figure 1-1 Components of the Temperature Verification System

Temperature Verification Tests

Use the Temperature Verification System to perform the following tests on your GeneAmp PCR Systems:

- **Calibration Verification Test** – Checks the temperature of the sample block against specifications for temperature accuracy
- **Temperature Non-Uniformity Test** – Checks the uniformity of sample block temperature from well to well

You can perform these tests as frequently as necessary, depending on the type of work your laboratory performs. For example, a laboratory that does forensic typing may need to validate the instrument before or after running samples to have the sample test results considered valid in a court case. Another laboratory may want to validate a protocol.

Typically, run the Calibration Verification Test at least once a year, and run the Temperature Non-Uniformity Test whenever you suspect variation in well-to-well temperature.

Running these tests checks that your thermal cycler is working properly.

Parts Included

Your kit includes

- Model 4500 Digital thermometer with 9V battery installed
- 0.2-mL Probe Assembly
- Cotton swabs
- Light mineral oil
- Temperature Verification Frames:
  - For system 2400 (PN N8031076)
  - For system 9600, system 9700, and system 2700(PN 4319613)
  - For system 9700, dual 96-well left and right frames (PN 4346188 and PN 4346189)

Figure 1-1 on page 1-3 illustrates the major components of the kit.

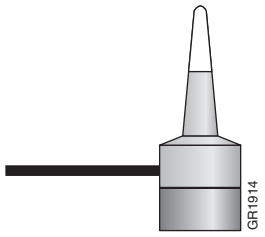
Note: If any part is damaged or missing, contact the shipping carrier and Applied Biosystems immediately. See “Damages, Claims, and Returns” on page B-4.

Recalibration

Applied Biosystems recommends that your Temperature Verification System be recalibrated once a year. For instructions on having your system recalibrated by the manufacturer, refer to Appendix A, “Recalibration.”

0.2-mL Probe Assembly

The 0.2-mL Probe Assembly, shown in the figure below, consists of a cone that measures the temperature of the sample well. The temperature is measured by a thermistor bead in the cone tip.

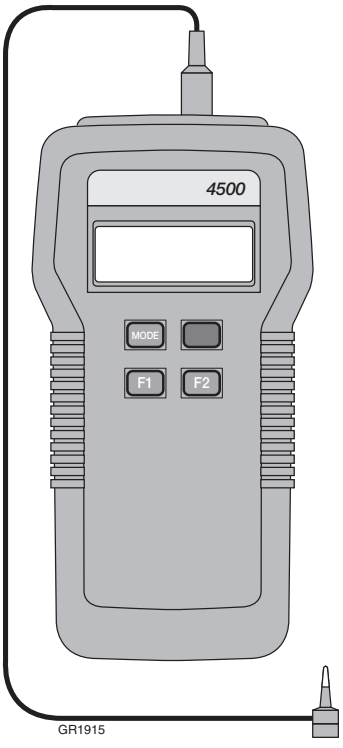


IMPORTANT! This probe assembly must be used only with 0.2-mL wells.

Digital Thermometer

Overview

The handheld digital thermometer, shown below, has a temperature range of 0 to 100 °C and is accurate to within ±0.1 °C.



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

Precautions

When you use the digital thermometer:

- Make sure the probe assembly is connected to the input connector at the top of the digital thermometer.
- To power on the digital thermometer, press the On/Off switch on its front.
- The temperature measured by the probe assembly appears on the digital thermometer display in degrees Celsius.
- When you complete a test, move the on/off switch to power off the digital thermometer.

Temperature Display Differences

The sample temperature displayed on the thermal cycler is different from the temperature displayed on the digital thermometer during heating or cooling transitions. This is because the thermal cycler measures sample temperature but the digital thermometer measures block temperature. The sample temperature displayed by the thermal cycler is a function of the tube type and the reaction volume.

Using the Probe While Running Programs

Applied Biosystems recommends that you use the probe assembly and digital thermometer only for the temperature Calibration Verification Test and the Temperature Non-Uniformity Test, which are described in this manual. If you use the probe assembly and digital thermometer while running programs other than those used in these two tests, be aware that the accuracy of the probe assembly decreases due to the effect of the heated sample block cover.

The heated cover normally operates at 105 °C. The effect of the heated cover on the probe assembly decreases as the temperature of the sample block approaches 99.9 °C.

Temperature Verification Tests for the System 9700 and System 2700

2

This chapter covers:

Overview

Materials

When you perform temperature verification tests on the System 9700 with a 96-Well Sample Block Module or System 2700, you use the materials provided in your kit.

Assembly

Figure 2-1 shows a properly assembled system. Note that the frame is positioned around the wells with the channel facing you, and the probe wire is threaded through the channel to prevent damaging the wire when the thermal cycler's heated cover is closed.

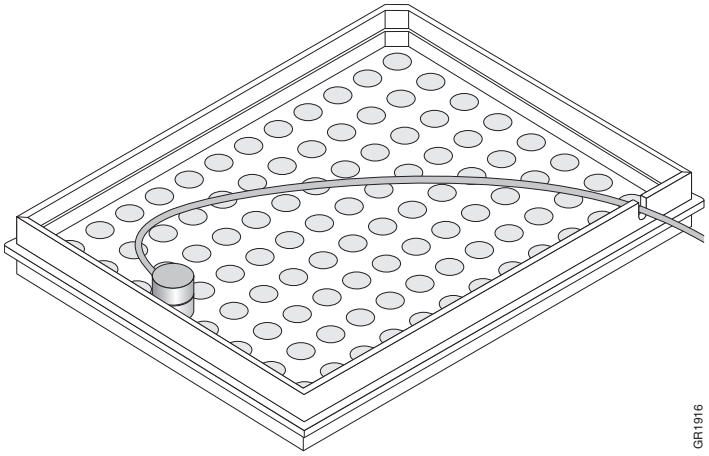


Figure 2-1 Proper assembly of the Temperature Verification System for System 9700 and System 2700

Calibration Verification Test

Overview

Use this test to verify the temperature calibration of your System 9700/2700 with a 0.2-mL Sample Block Module.

The Calibration Verification Test consists of the following subprocedures, which must be done in order:

PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.

Required Materials

This test requires the 0.2-mL Sample Block Module Temperature Verification Kit (PN 4317939), which includes:

- Cotton swabs
- Light mineral oil
- 9700/2700 Temperature Verification Frame
- 0.2-mL Probe Assembly
- Model 4500 Digital thermometer with 9V battery installed

Setting Up the 0.2-mL Probe Assembly

To set up the 0.2-mL Probe Assembly:

1. For system 9700, if the heated cover is in the forward position, lift the lever, then slide the heated cover back.

   For system 2700, lift the lever and open the hinged heated cover.

2. Place the 9700/2700 Temperature Verification Frame on the sample block.
3. Using a cotton swab, coat well **A6** with mineral oil.
4. Place the 0.2-mL Probe Assembly into well **A6**.
5. Thread the probe wire through the channel in the 9700/2700 Temperature Verification Frame to prevent damage to the probe and lead wires. (See Figure 2-1 on page 2-2.)
6. Make sure the probe is connected to the digital thermometer.

7. For the 9700 system, slide the heated cover forward and pull the lever down.

   For the 2700 system, pull the lever down to engage the heated cover and 9700/2700 Temperature Verification Frame.

   IMPORTANT! The probe must be seated properly and the heated cover closed carefully. If the probe wire is crushed when the heated cover is closed, the probe can be damaged.

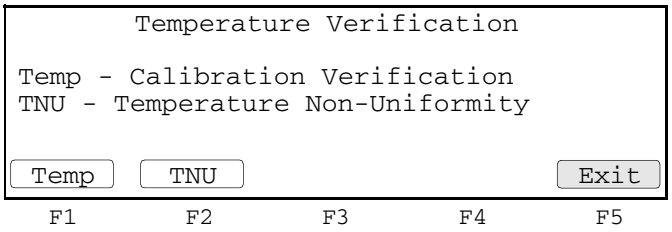
8. Power on the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for a detailed description on operating the Model 4500 digital thermometer.

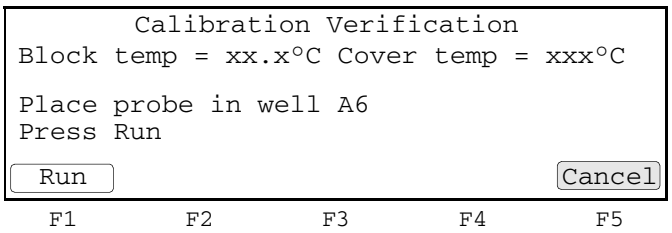
Configuring the System 9700/2700

To configure the system 9700/2700 for the Calibration Verification Test:

1. Power on the system 9700/2700. The Main menu appears.
2. Press **F4** (Util)**.** The Utilities screen appears.
3. Press **F1** (Diag). The Diagnostics screen appears.
4. Press **F3** (TmpVer). The Temperature Verificatio**n** screen appears.



5. Press **F1** (Temp). The system 9700/2700 is automatically configured for the Calibration Verification Test and the Calibration Verification screen appears.



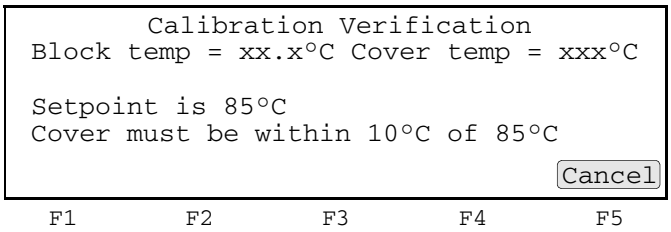
Running the Test

In this test, you take temperature readings of the sample well at two different setpoint temperatures using the 0.2-mL Probe Assembly.

Note: Press **F5** (Cancel) if you want to end the test.

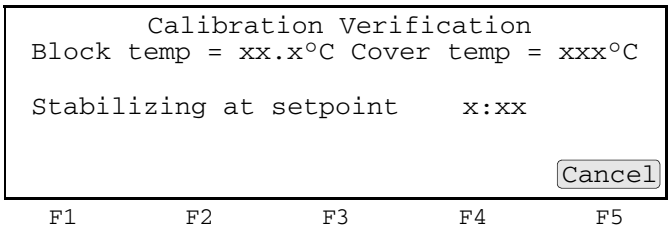
To run the Calibration Verification Test:

1. Press **F1** (Run) to start the Calibration Verification Test. The Calibration Verification screen appears with the setpoint value displayed.



Note: The cover must be at 85 °C ±10 °C. It may take several minutes for the system to ramp up.

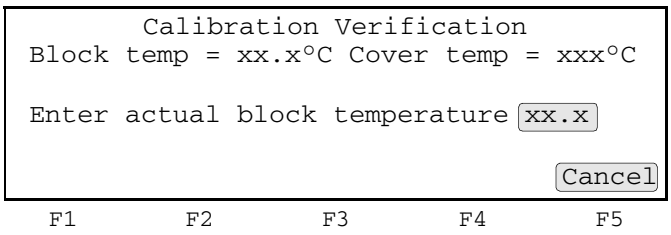
The Calibration Verification screen counts down the time until the setpoint is reached.



2. When the "Stabilizing at setpoint" value decreases to 0, read the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

3. Using the numeric keys, type the value displayed on the digital thermometer in the "Enter actual block temperature" field.

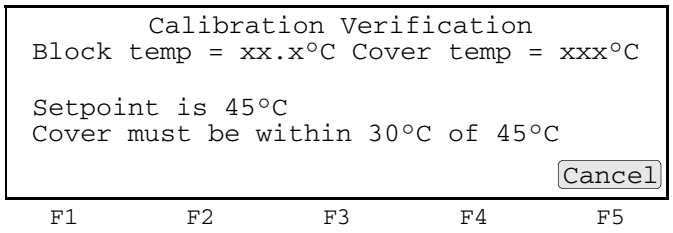


   Note: The digital thermometer displays a four-digit value; round this off to three digits before typing it in the Calibration Verification screen.

   Note: Record this value on the Calibration Verification Test Data Sheet (page 2-13) to keep a permanent record of the test.

4. Press **Enter**.

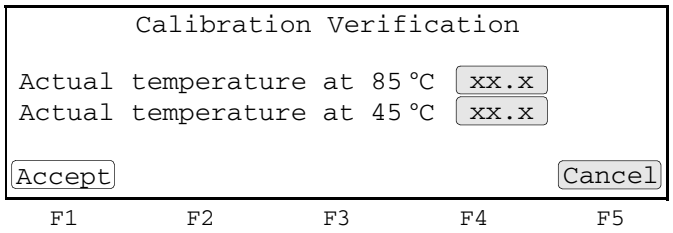
   The system 9700/2700 automatically begins the second temperature reading (45 °C setpoint). The Calibration Verification screen appears with the setpoint value displayed.



Note: The cover must be at 45 °C ±30 °C. It may take several minutes for the system to ramp up.

5. Repeat steps 2 through 4 for the second temperature reading.

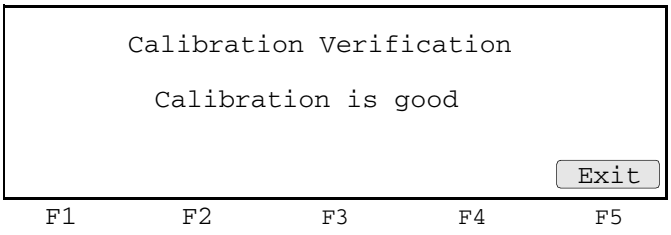
   The system 9700/2700 evaluates the calibration of the sample block temperature for the setpoint values you entered and displays the results. A summary screen appears at the conclusion of the test.

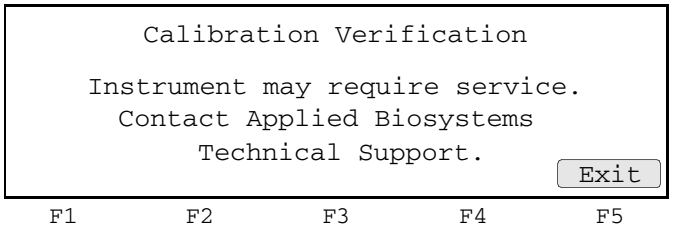


6. If you entered values on the Calibration Verification Test Data Sheet (page 2-13), compare those values with the actual test results.
7. Press **F1** (Accept).

Evaluating the Results

When the system 9700/2700 completes the Calibration Verification Test, one of two screens appears, depending on the test results. See the table below to evaluate the results.

If the sample block module...	Then the...
Is properly calibrated	Calibration Verification screen appears with the following message displayed. 

If the sample block module...	Then the...
Does not pass the Calibration Verification Test	Calibration Verification screen appears with the following message displayed.  • If the test fails, repeat the procedure to make sure the digital thermometer was not misread or that data entry errors were not made. • If the test fails again, contact Applied Biosystems Technical Support.

Ending the Test

To end the test:

1. Press **F5** (Exit).
2. Remove the 0.2-mL Probe Assembly from the sample block.
3. Power off the digital thermometer and clean off the oil.

   Wait for the sample block to reach room temperature (~25 °C), then remove the 9700/2700 Temperature Verification Frame from the sample block.

   WARNING **PHYSICAL INJURY HAZARD.** Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.
4. Clean the oil off the sample block.

Temperature Non-Uniformity Test

Overview

Use this test to verify the temperature uniformity of the system 9700/2700 with a 0.2-mL Sample Block Module.

The Temperature Non-Uniformity Test consists of the following subprocedures, which must be done in order:

PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.

Required Materials

This test requires the 0.2-mL Sample Block Module Temperature Verification Kit (PN 4317939), which includes:

- Cotton swabs
- Light mineral oil
- 9700/2700 Temperature Verification Frame
- 0.2-mL Probe Assembly
- Model 4500 digital thermometer with 9V battery installed

Setting Up the 0.2-mL Probe Assembly

To set up the 0.2-mL Probe Assembly:

1. For system 9700, if the heated cover is in the forward position, lift the lever, then slide the heated cover back.

   For system 2700, lift the lever and open the hinged heated cover.

2. Place the 9700/2700 Temperature Verification Frame on the sample block.

3. Use a cotton swab to coat the following wells with mineral oil:
   A1, A12, C4, C9, F4, F9, H1, H12.

4. Place the 0.2-mL Probe Assembly into well A1.

   Note: As the test progresses, you move the 0.2-mL Probe Assembly to each of the test wells.

5. Thread the probe wire through the channel in the 9700/2700 Temperature Verification Frame to prevent damage to the probe and lead wires. (See Figure 2-1 on page 2-2.)

6. Make sure the probe is connected to the digital thermometer.

7. For system 9700, slide the heated cover forward and pull the lever down.

   For system 2700, pull the lever down to engage the heated cover and 9700/2700 Temperature Verification Frame.

   IMPORTANT! The probe must be seated properly and the heated cover closed carefully. If the probe wire is crushed when the heated cover is closed, the probe can be damaged.

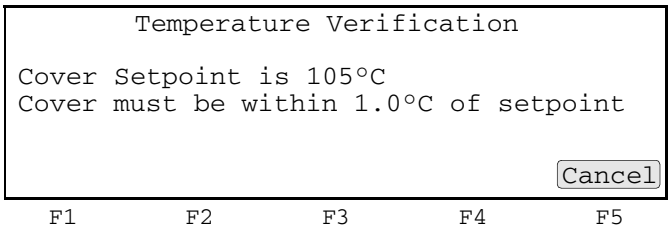
8. Power on the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

Configuring the System 9700/2700

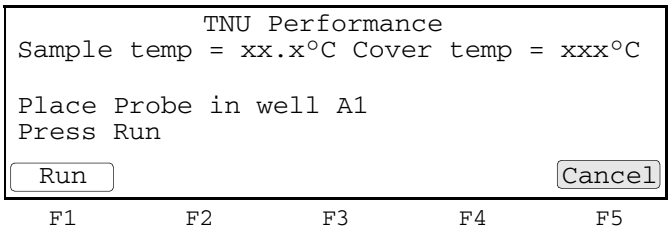
To configure the 9700/2700 system :

1. Start up the 9700/2700 system. The Main menu appears.
2. Press **F4** (Util)**.** The Utilities screen appears.
3. Press **F1** (Diag). The Diagnostics screen appears.
4. Press **F3** (TempVer). The Temperature Verification screen appears.



5. Press **F2** (TNU).

   The 9700/2700 system is automatically configured for the Temperature Non-Uniformity Test, starting with the setpoint of 37 °C. Then the TNU Performance screen appears.



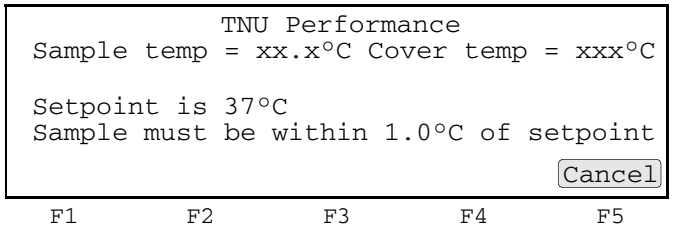
Running the Test

The Temperature Non-Uniformity Test uses the 0.2-mL Probe Assembly to test the temperature uniformity of 8 different wells in the sample block.

Note: Press F5 (Cancel) if you want to exit the test.

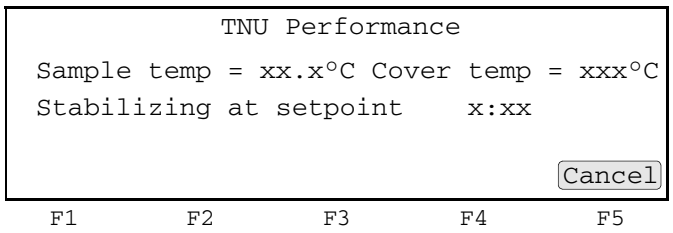
To run the Temperature Non-Uniformity Test:

1. Press **F1** (Run). The Temperature Non-Uniformity Test starts, and the TNU Performance screen appears with the setpoint value displayed.



Note: The sample block must be at 37 °C ±1.0 °C.

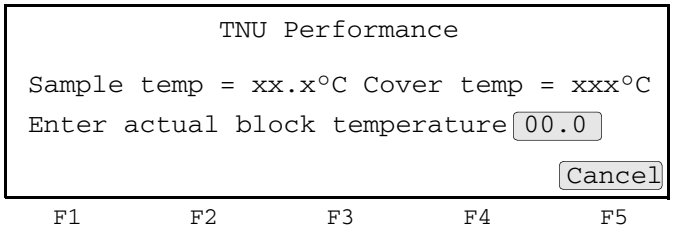
The TNU Performance screen counts down the time until the setpoint is stabilized.



2. When the "Stabilizing at setpoint" value decreases to 0, read the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

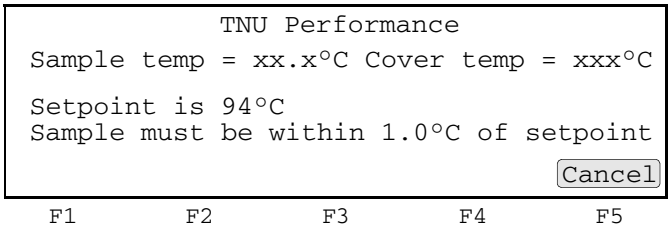
3. Using the numeric keys, type the value displayed on the digital thermometer in the "Enter actual block temperature" field.



Note: The digital thermometer displays a four-digit value; round this off to three digits before typing it in the TNU Performance screen.

Note: Record this value on the Temperature Non-Uniformity Test Data Sheet (page 2-14) to keep a permanent record of the test.

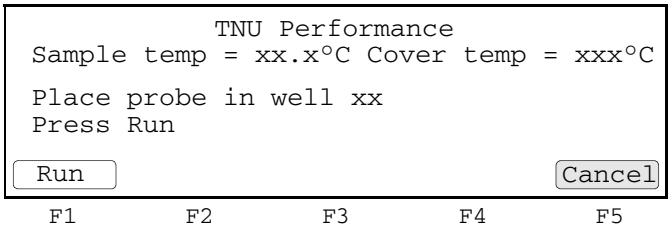
4. Press **Enter**. The system 9700/2700 automatically begins the second reading (94 °C setpoint) and the TNU Performance screen appears with the setpoint value displayed.



Note: The sample block must be at 94 °C ±1.0 °C. In addition, the cover must be at 105 °C ±1 °C. It may take several minutes for the system 9700/2700 to stabilize at the setpoint temperature.

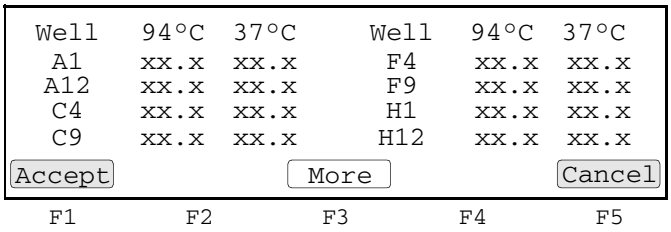
5. Repeat steps 2 through through 4 for the second reading.

6. Press **Enter**. The TNU Performance screen appears with the following prompt:



7. Slide the heated cover back (system 9700) or open the hinged heated cover (system 2700). Repeat steps 4 through 7 of "Setting Up the 0.2-mL Probe Assembly" on page 2-8 and steps 2 through 7 of this procedure. Complete these steps for all 8 wells to be tested: A1, A12, C4, C9, F4, F9, H1, H12.

8. The system 9700/2700 evaluates the uniformity of the sample block temperature for the setpoint values you entered and displays the results. A summary screen appears at the conclusion of the test.

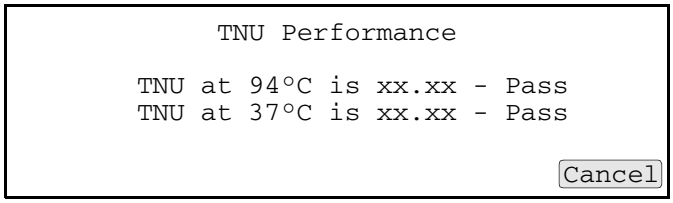
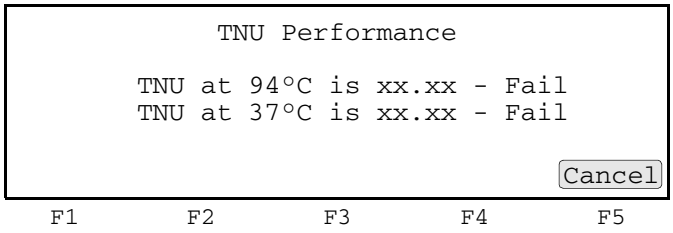


If you entered values on the Temperature Non-Uniformity Test Data Sheet (page 2-14), compare those values with the actual test results.

9. Press **F1** (Accept).

Evaluating the Results

When the system 9700/2700 completes the Temperature Non-Uniformity Test, the TNU Performance screen appears. See the table below to evaluate the results.

If the...	Then...
Temperature of the sample block wells is uniform,	"Pass" appears after each setpoint temperature. 
Temperature variation of the sample block wells exceeds performance specifications,	"Fail" appears after the setpoint temperature(s) for which the test failed.  • If the test fails, repeat the procedure to make sure the digital thermometer was not misread or that data entry errors were not made. • If the test fails again, contact Applied Biosystems Technical Support.

Ending the Test

To end the test:

1. Press **F5** (Cancel).
2. Remove the 0.2-mL Probe Assembly from the sample block.
3. Power off the digital thermometer and clean off the oil.
4. Wait for the sample block to reach room temperature (~25 °C), then remove the 9700/2700 Temperature Verification Frame from the sample block.

   WARNING **PHYSICAL INJURY HAZARD.** Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.
5. Clean the oil off the sample block.

Data Sheet: Calibration Verification Test

When you run the Calibration Verification Test, record the setpoint values for **well A6** on this data sheet. At the end of the Calibration Verification Test, check the values displayed on the system 9700/2700 against the values recorded here.

Note: You can photocopy this page.

Date	Tested By	Probe Serial No.	Thermometer Serial No.	Setpoint Value: Well A6	
				85 °C	45 °C

Data Sheet: Temperature Non-Uniformity Test

When you run the Temperature Non-Uniformity Test, record the setpoint values for the wells listed on this data sheet. At the end of the Temperature Non-Uniformity Test, check the values displayed on the system 9700/2700 against the values recorded here.

Note: If desired, you can photocopy this page.

Date		
Tested By		
Probe Serial No.		
Thermometer Serial No.		
Setpoint Value	**94 °C**	**37 °C**
A1		
A12		
C4		
C9		
F4		
F9		
H1		
H12		

Temperature Verification Tests for the System 9700 (Dual 96-Well Module)

3

This chapter covers:

Overview

Materials

When you perform temperature verification tests on the System 9700 with a Dual 96-Well Sample Block Module, you use the materials provided in your kit.

Assembly

Figure 3-1 shows the right frame of a properly assembled system. Note that the probe wire is threaded through the channel to prevent damage to the wire when the thermal cycler's heated cover is closed.

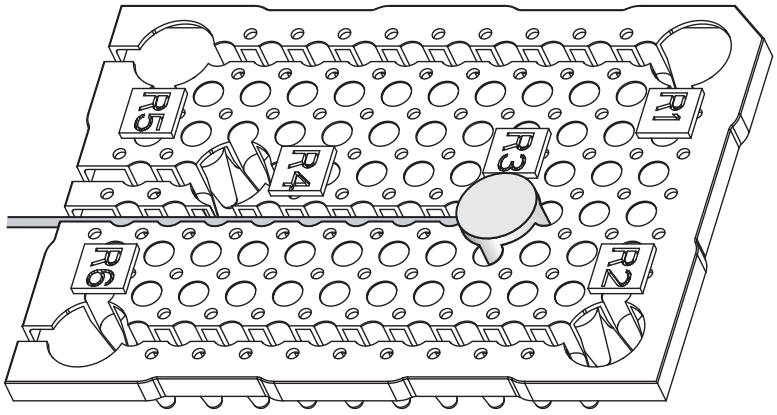


Figure 3-1 Proper assembly of the Temperature Verification System for System 9700 with a dual 96-well sample block module (right frame shown)

Calibration Verification Test

Overview

Use this test to verify the temperature calibration of a system 9700 with a Dual 96-Well Sample Block Module.

The Calibration Verification Test consists of the following subprocedures, which must be done in order:

PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.

Required Materials

This test requires the 0.2-mL Sample Block Module Temperature Verification Kit (PN 4317939), which includes:

- Cotton swabs
- Light mineral oil
- Left and Right Dual 96-Well Block Temperature Verification Plates
- 0.2-mL Probe Assembly
- Model 4500 digital thermometer with 9V battery installed

Setting Up the 0.2-mL Probe Assembly

To set up the 0.2-mL Probe Assembly:

1. For System 9700 with a manual Dual 96-Well Sample Block Module – If the heated cover is in the forward position, lift the lever, then slide the heated cover back.

   For System 9700 with an Auto-Lid Dual 96-Well Sample Block Module – If the heated cover is in the forward position, lift the lever, then press the red button to slide the heated cover back.

2. Place both Dual 96-Well Temperature Verification Plates on the sample block. The plate labeled with L1 to L6 is for the left sample block. The plate labeled with R1 to R6 is for the right sample block. Position the plates so the angled corners face away from you.

   Note: The plates are used as guides to help you locate the probes within the sample blocks.

3. Using a cotton swab, coat well **R3** with mineral oil.

4. Place the 0.2-mL Probe Assembly into well **R3**.

5. Thread the probe wire through the channel in the Dual 96-Well Temperature Verification Plate to prevent damage to the probe and lead wires. (See Figure 3-1 on page 3-2.)
6. Make sure the probe is connected to the digital thermometer.
7. For System 9700 with manual Dual 96-Well Sample Block Module – Slide the heated cover forward then pull the lever down.

   For System 9700 with Auto-Lid Dual 96-Well Sample Block Module – Press the red button to slide and close the heated cover.

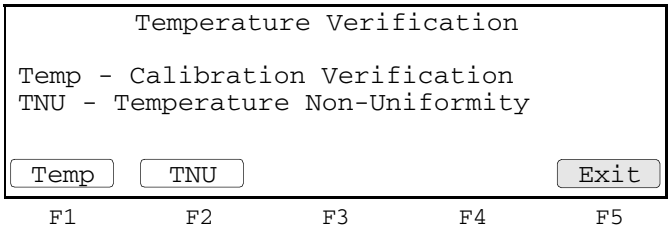
   IMPORTANT! The probe must be seated properly and the heated cover closed carefully. If the probe wire is crushed when the heated cover is closed, the probe can be damaged.
8. Power on the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

Configuring the System 9700

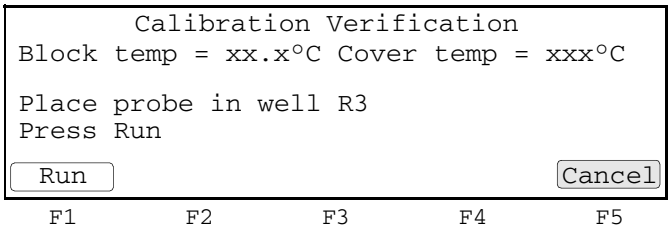
To configure the 9700 system for the Calibration Verification Test:

1. Start up the 9700 system. The Main menu appears.
2. Press **F4** (Util)**.** The Utilities screen appears.
3. Press **F1** (Diag). The Diagnostics screen appears.
4. Press **F3** (TmpVer). The Temperature Verification screen appears.



5. Press **F1** (Temp).

   The 9700 system is automatically configured for the Calibration Verification Test, and the Calibration Verification screen appears.



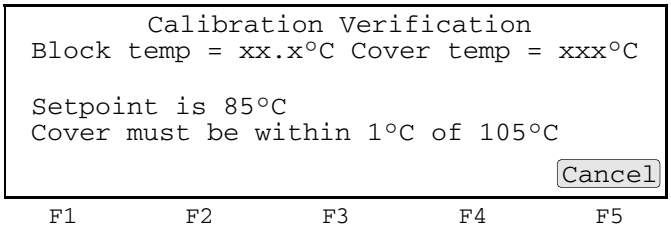
Running the Test

In this test, you take temperature readings of the sample well at two different set points using the 0.2-mL Probe Assembly.

Note: Press **F5** (Cancel) if you want to exit the test.

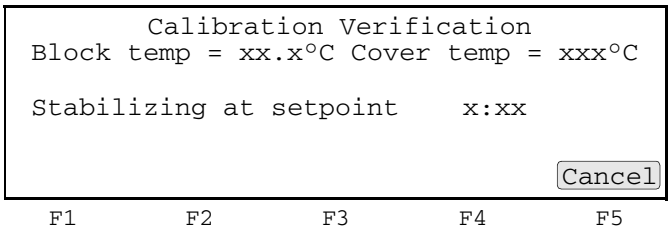
To run the Calibration Verification Test:

1. Press **F1** (Run). The Calibration Verification screen appears with the setpoint value displayed.



Note: The cover must be at 105 °C ±1 °C. It may take several minutes for the system to ramp up.

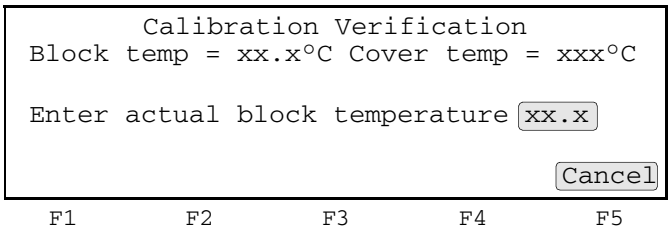
The Calibration Verification screen counts down the time until the setpoint is reached.



2. When the "Stabilizing at setpoint" value decreases to 0, read the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

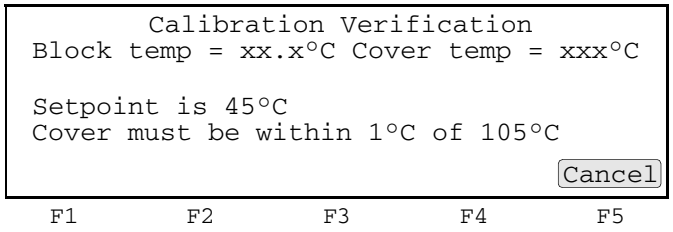
3. Using the numeric keys, type the value displayed on the digital thermometer in the "Enter actual block temperature" field.



Note: The digital thermometer displays a four-digit value; round this off to three digits before typing it in the Calibration Verification screen.

Note: Record this value on the Calibration Verification Test Data Sheet (page 3-13) to keep a permanent record of the test.

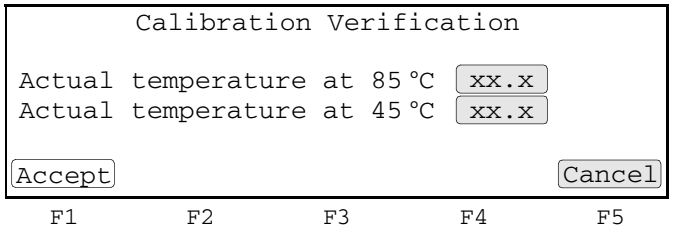
4. Press **Enter**. The 9700 system automatically begins the second reading (45 °C setpoint), and the Calibration Verification screen appears with the setpoint value displayed.



Note: The cover must be at 105 °C ±1 °C. It may take several minutes for the system to ramp up.

5. Repeat steps 2 through 4 for the second temperature reading.

   The 9700 system evaluates the calibration of the sample block temperature for the setpoint values you entered and displays the results. A summary screen appears at the conclusion of the test.



6. If you entered values on the Calibration Verification Test Data Sheet (page 3-13), compare those values with the actual test results.
7. Press **F1** (Accept).

Evaluating the Results

When the system 9700 completes the Calibration Verification Test, one of two screens appears. See the table below to evaluate the results.

If the sample block module...	Then the...
Is properly calibrated	Calibration Verification screen appears with the following message displayed. Calibration Verification Calibration is good Exit F1 F2 F3 F4 F5
Does not pass the Calibration Verification Test	Calibration Verification screen appears with the following message displayed. Calibration Verification Instrument may require service. Contact Applied Biosystems Technical Support. Exit F1 F2 F3 F4 F5 • If the test fails, repeat the procedure to make sure the digital thermometer was not misread or that data entry errors were not made. • If the test fails again, contact Applied Biosystems Technical Support.

Ending the Test

To end the test:

1. Press **F5** (Exit).
2. Remove the 0.2-mL Probe Assembly from the sample block.
3. Power off the digital thermometer and clean off the oil.
4. Wait for the sample block to reach room temperature (~25 °C), then remove the Dual 96-Well Temperature Verification Plates from the sample block.

   WARNING **PHYSICAL INJURY HAZARD.** Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.

5. Clean the oil off the sample block.

Temperature Non-Uniformity Test

Overview

Use this test to verify the temperature uniformity of the system 9700 with a Dual 96-Well Sample Block Module.

The Temperature Non-Uniformity Test consists of the following subprocedures, which must be done in order:

Subprocedure	See Page
Setting Up the 0.2-mL Probe Assembly	3-8
Configuring the System 9700	3-9
Running the Test	3-10
Evaluating the Results	3-12
Ending the Test	3-12

PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.

Required Materials

This test requires the 0.2-mL Sample Block Module Temperature Verification Kit (PN 4317939), which includes:

- Cotton swabs
- Light mineral oil
- Left and Right Dual 96-Well Block Temperature Verification Plates
- 0.2-mL Probe Assembly
- Model 4500 digital thermometer with 9V battery installed

Setting Up the 0.2-mL Probe Assembly

To set up the 0.2-mL Probe Assembly:

1. For the 9700 system with a manual Dual 96-Well Sample Block Module – If the heated cover is in the forward position, lift the lever, then slide the heated cover back.

   For the 9700 system with an Auto-Lid Dual 96-Well Sample Block Module – If the heated cover is in the forward position, lift the lever, then press the red button to slide the heated cover back.

2. Place both Dual 96-Well Temperature Verification Plates on the sample block. The plate labeled with L1 to L6 is for the left sample block. The plate labeled with R1 to R6 is for the right sample block. Position the plates so the angled corners face away from you.

   Note: The plates are used as guides to help you locate the probes within the sample blocks.

3. Use a cotton swab to coat wells L1 to L6 and R1 to R6 with mineral oil.

4. Place the 0.2-mL Probe Assembly into well L1.
   As the test progresses, you move the 0.2-mL Probe Assembly to each of the test wells (L1 to L6 and R1 to R6).
5. Thread the probe wire through the channel in the Dual 96-Well Temperature Verification Plate to prevent damage to the probe and lead wires.
   (See Figure 3-1 on page 3-2.)
6. Make sure the probe is connected to the digital thermometer.
7. For the 9700 System with manual Dual 96-Well Sample Block Module – Slide the heated cover forward and pull the lever down.

   For the 9700 System with Auto-Lid Dual 96-Well Sample Block Module – Press the red button to slide and close the heated cover.

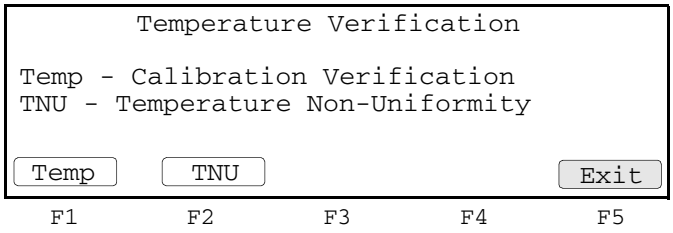
   IMPORTANT! The probe must be seated properly and the heated cover closed carefully. If the probe wire is crushed when the heated cover is closed, the probe can be damaged.
8. Turn on the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermomete.

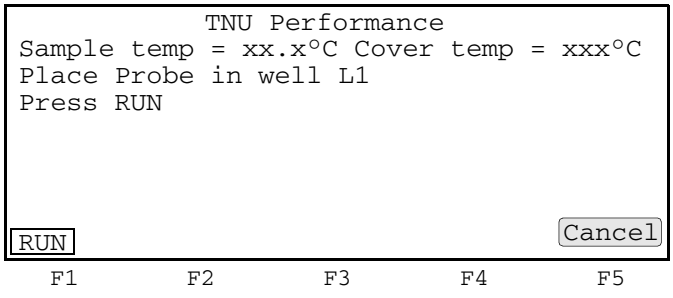
Configuring the System 9700

To configure the 9700 system:

1. Start up the 9700 system. The Main menu appears.
2. Press **F4** (Util)**.** The Utilities screen appears.
3. Press **F1** (Diag). The Diagnostics screen appears.
4. Press **F3** (TempVer). The Temperature Verification screen appears.



5. Press **F2** (TNU). The 9700 system is automatically configured for the Temperature Non-Uniformity Test, starting with the setpoint of 95 °C, and the TNU Performance screen appears. The following screen appears when the cover reaches the setpoint.



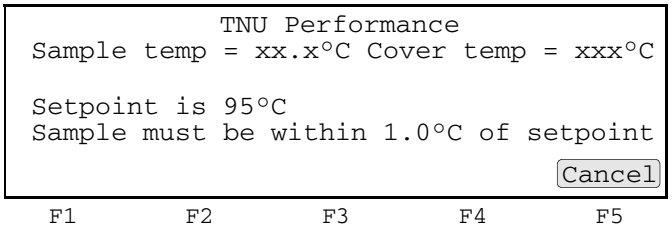
Running the Test

The Temperature Non-Uniformity Test uses the 0.2-mL Probe Assembly to test the temperature uniformity of 6 different wells in each sample block.

Note: Press **F5** (Cancel) if you want to exit the test.

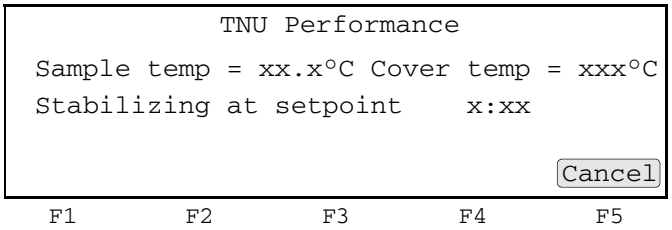
To run the Temperature Non-Uniformity Test:

1. Press **F1** (Run). The Temperature Non-Uniformity Test starts, and the TNU Performance screen appears with the setpoint value displayed.



Note: The sample block must be at 95 °C ±1.0 °C. In addition, the cover must be at 105 °C ±1.0 °C. It may take several minutes for the system 9700 to stabilize at the setpoint temperature.

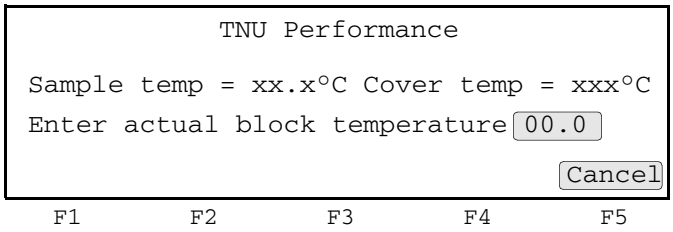
The TNU Performance screen counts down the time until the setpoint is stabilized.



2. When the "Stabilizing at setpoint" value decreases to 0, read the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

3. Using the numeric keys, type the value displayed on the digital thermometer in the "Enter actual block temperature" field.



Note: The digital thermometer displays a four-digit value; round this off to three digits before typing it in the TNU Performance screen.

Note: Record this value on the Temperature Non-Uniformity Test Data Sheet (page 3-14) to keep a permanent record of the test.

4. Press **Enter**. The 9700 system automatically begins the second reading (55 °C setpoint), and the TNU Performance screen appears with the setpoint value displayed.

```
              TNU Performance
Sample temp = xx.x°C Cover temp = xxx°C

Setpoint is 55°C
Sample must be within 1.0°C of setpoint
                                   Cancel
   F1        F2        F3        F4        F5
```

Note: The sample block must be at 55 °C ±1.0 °C. In addition, the cover must be at 105 °C ±1.0 °C. It may take several minutes for the 9700 system to stabilize at the setpoint temperature.

5. Repeat steps 2 through 4 for the second reading.

6. Press **Enter**. The TNU Performance screen appears with the following prompt:

```
              TNU Performance
Sample temp = xx.x°C Cover temp = xxx°C

Place probe in well xx
Press Run

 Run                               Cancel
   F1        F2        F3        F4        F5
```

7. For the System 9700 with a manual Dual 96-Well Sample Block Module – Slide the heated cover forward and pull the lever down.

   For the System 9700 with an Auto-Lid Dual 96-Well Sample Block Module – Press the red button to slide and close the heated cover.

   Repeat steps 4 through 7 of "Setting Up the 0.2-mL Probe Assembly" on page 3-8 and steps 2 through 7 of this procedure. Complete these steps for all the remaining 11 wells to be tested (L2 to L6 and R1 to R6).

   The 9700 system evaluates the uniformity of the sample block temperature for the setpoint values you entered and displays the results. A summary screen appears at the conclusion of the test.

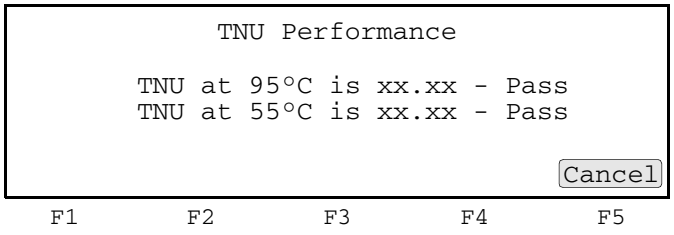
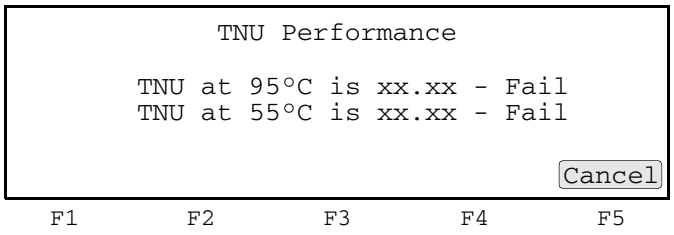
```
 Well   95°C  55°C     Well   95°C  55°C
  L1    xx.x  xx.x      L5    xx.x  xx.x
  L2    xx.x  xx.x      L6    xx.x  xx.x
  L3    xx.x  xx.x      R1    xx.x  xx.x
  L4    xx.x  xx.x      R2    xx.x  xx.x
Accept          More              Cancel
   F1        F2        F3        F4        F5
```

8. If you entered values on the Temperature Non-Uniformity Test Data Sheet (page 3-14) , compare those values with the actual test results.

9. Press **F1** (Accept).

Evaluating the Results

After the 9700 system completes the Temperature Non-Uniformity Test, the TNU Performance screen appears. See the table below to evaluate the results.

If the...	Then...
Temperature of the sample block wells is uniform,	"Pass" appears after each setpoint temperature. 
Temperature variation of the sample block wells exceeds performance specifications,	"Fail" appears after the setpoint temperature(s) for which the test failed.  • If the test fails, repeat the procedure to make sure the digital thermometer was not misread or that data entry errors were not made. • If the test fails again, contact Applied Biosystems Technical Support.

Ending the Test

To end the test:

1. Press **F5** (Cancel).
2. Remove the 0.2-mL Probe Assembly from the sample block.
3. Power off the digital thermometer and clean off the oil.
4. Wait for the sample block to reach room temperature (~25 °C), then remove the Dual 96-Well Temperature Verification Plates from the sample block.

   WARNING **PHYSICAL INJURY HAZARD.** Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.
5. Clean the oil off the sample block.

Data Sheet: Calibration Verification Test

When you run the Calibration Verification Test, record the setpoint values for **well R3** on this data sheet. At the end of the Calibration Verification Test, check the values displayed on the system 9700 against the values recorded here.

Note: You can photocopy this page.

Date	Tested By	Probe Serial No.	Thermometer Serial No.	Setpoint Value: Well R3	
				85 °C	45 °C

Data Sheet: Temperature Non-Uniformity Test

When you run the Temperature Non-Uniformity Test, record the setpoint values for the wells L1 to L6 and R1 to R6 listed on this data sheet. At the end of the Temperature Non-Uniformity Test, check the values displayed on the 9700 system against the values recorded here.

Note: You can photocopy this page.

Date		
Tested By		
Probe Serial No.		
Thermometer Serial No.		
Setpoint Value	**95 °C**	**55 °C**
L1		
L2		
L3		
L4		
L5		
L6		
R1		
R2		
R3		
R4		
R5		
R6		

Temperature Verification Tests for the System 9600

4

This chapter covers:

Overview

Materials

When you perform temperature verification tests on the System 9600, you use the materials provided in your kit.

Assembly

Figure 4-1 shows a properly assembled system. Note that the frame is positioned around the wells with the channel facing you, and the probe wire is threaded through the channel to prevent damaging the wire when the thermal cycler's heated cover is closed.

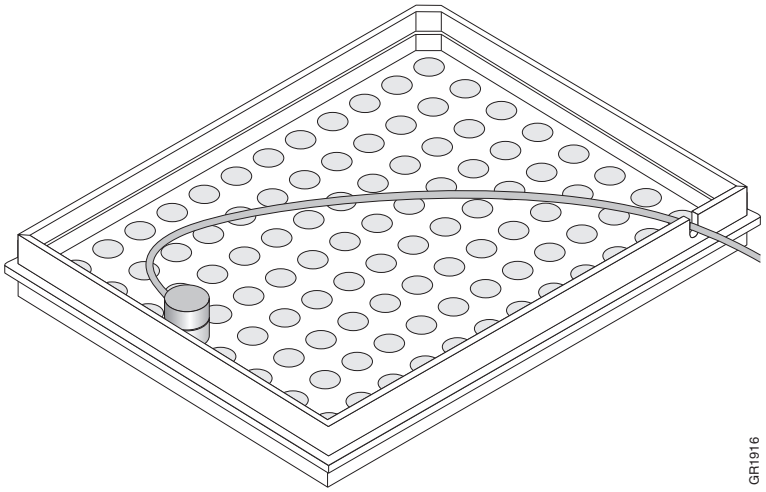


Figure 4-1 Proper assembly of the Temperature Verification System for System 9600

Calibration Verification Test

Overview

Use this test to verify the temperature calibration of your 9600 system.

The Calibration Verification Test consists of several subprocedures, which must be done in order:

WARNING **PHYSICAL INJURY HAZARD.** Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.

Required Materials

This test requires the 0.2-mL Temperature Verification Kit (PN 4317939), which includes:

- Cotton swabs
- Light mineral oil
- 9600 Temperature Verification Frame
- 0.2-mL Probe Assembly
- Model 4500 digital thermometer with 9V battery installed

Setting Up the 0.2-mL Probe Assembly

To set up the 0.2-mL Probe Assembly:

1. If the heated cover is in the forward position, turn the knob completely counter clockwise, then slide the heated cover back.
2. Place the 9600 Temperature Verification Frame on the sample block.
3. Using a cotton swab, coat well **E1** with mineral oil.
4. Place the 0.2-mL Probe Assembly into well **E1**.
5. Thread the probe wire through the channel in the 9600 temperature verification frame to prevent damage to the probe and lead wires. (See Figure 4-1 on page 4-2.)
6. Make sure the probe is connected to the digital thermometer.

7. Slide the heated cover forward, then turn the cover knob clockwise until the white mark on the knob is aligned with the white mark on the cover.

   IMPORTANT! The probe must be seated properly and the heated cover closed carefully. If the probe wire is crushed when the heated cover is closed, the probe can be damaged.

8. Turn on the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for a detailed description on operating the Model 4500 digital thermometer.

Running the Test

To run the Calibration Verification Test:

1. Start up the 9600 system. The Main menu appears.
2. Press the **OPTION** key three times to move the cursor to **UTIL**, then press **ENTER**. The Utilities menu appears.

```
Select Function
DIR-CONFIG-DIAG-DEL
```

3. Press the **OPTION** key twice to move the cursor to **DIAG**, then press **ENTER**. The following menu appears:

```
Enter Diag Test #1
REVIEW History file
```

4. Press 5, then press **ENTER** to run the Verify Calibration Diagnostic Test (Test #5).

   Note: To ensure maximum accuracy, the temperatures of the heated cover and the sample block are the same in this test. This prevents the heated cover from affecting the accuracy of the probe assembly.

   The temperature of the sample block and heated cover increases to 40 °C, and the following display appears:

```
Going to 40°C...
Cvr = xxC Blk = xx.xC
```

   This display shows the current temperature of the block cover (Cvr = xxC) and sample block (Blk = xx.xC).

   When the temperature of the block cover is within 10 °C of the sample block temperature, the following display appears:

```
Wait 3 minutes
Time=MM:SS Blk=40.0C
```

   This display shows the current sample block temperature (“Blk=40.0C”) and a clock that counts up from 0 in minutes and seconds (“Time=MM:SS”).

When the clock reaches 3 minutes, the following display appears:

```
Record Temperature
Time=MM:SS Blk=95.0C
```

5. Measure the temperature of well E1 using the digital thermometer. Record this temperature as T(40).
6. Press **ENTER**.

   The temperature of the sample block and heated cover goes to 95 °C, and the following display appears:

```
Going to 95°C...
Cvr = xxC Blk = xx.xC
```

   This display shows the current temperature of the block cover (Cvr = xxC) and sample block (Blk = xx.xC).

   When the temperature of the block cover is within 10 °C of the sample block temperature, the following display appears:

```
Wait 3 Minutes
Time=MM:SS Blk=95.0C
```

   This display shows the current sample block temperature ("Blk=95.0C") and a clock that counts up from 0 in minutes and seconds ("Time=MM:SS").

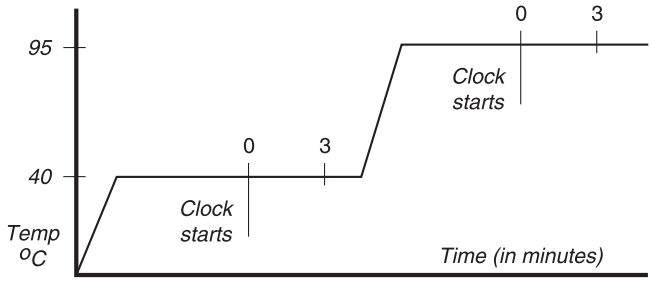
   When the clock reaches 3 minutes, the following display appears:

```
Record Temperature
Time=MM:SS Blk=95.0C
```

7. Measure the temperature of well E1 using the digital thermometer. Record this temperature as T(95).

   IMPORTANT! To end the test at any time, press the **STOP** key. This returns you to the "Review History File" display. Press **5** and then press **ENTER** to return to the Verify Calibration Diagnostic test.

The figure below illustrates temperatures during the Calibration Verification Test.



Calculating Test Results

Use the following information to calculate the results of the test. Refer to the calibration label in your user's manual for the High and Low Offset values.

Note: If there is more than one system 9600 in your laboratory, verify that the serial number on the calibration label matches the serial number on the instrument you are testing.

Average Block Temperature at the 95 °C Hold

Use the following formula to calculate the average block temperature at the 95 °C hold:

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

If the block average is more than 0.75 °C above or below 95 °C, your system 9600 must be recalibrated.

For example:

If the measured temperature of well E1 was 95.2 °C, and the High Offset printed on your calibration label is –0.1, you would make the following calculation:

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

In this example, because 95.3 °C does not differ by ±0.75 °C from your programmed target temperature, your instrument would not need to be recalibrated.

Note: The offset is the number of degrees Celsius that the temperature of well E1 differed from the average temperature of the block when the instrument was calibrated at the factory.

Average Block Temperature at the 40 °C Hold

Use the following formula to calculate the average block temperature at the 40 °C hold:

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

If the block average is more than 0.75 °C above or below 40 °C, your system 9600 must be recalibrated.

For example:

If the measured temperature of well E1 was 39.9 °C, and the Low Offset printed on your calibration label is +0.1, you would make the following calculation:

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

In this example, because 39.8 °C does not differ by ±0.75 °C from your programmed target temperature, your instrument would not need to be recalibrated.

Ending the Test

When you have completed all measurements, end the test.

To end the test:

1. Remove the 0.2-mL Probe Assembly from the sample block.
2. Power off the digital thermometer and clean off the oil.
3. Wait for the sample block to reach room temperature (~25 °C), then remove the 9600 Temperature Verification Frame from the sample block.

   PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.
4. Clean the oil off the sample block.

Temperature Non-Uniformity Test

Overview

Use this test to verify the temperature uniformity of the system 9600.

The Temperature Non-Uniformity Test consists of the following subprocedures, which must be done in order:

WARNING **PHYSICAL INJURY HAZARD.** Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.

Required Materials

This test requires the 0.2-mL Temperature Verification Kit (PN 4317939), which includes:

- Cotton swabs
- Light mineral oil
- 9600 Temperature Verification Frame
- 0.2-mL Probe Assembly
- Model 4500 digital thermometer with 9V battery installed

Setting Up the 0.2-mL Probe Assembly

To set up the 0.2-mL Probe Assembly:

1. If the heated cover is in the forward position, turn the knob completely counterclockwise, then slide the heated cover back.
2. Using a cotton swab, coat the following wells with mineral oil:

   A1, **A4**, **A8**, **A12**, **C1**, **C4**, **C8**, **C12**, **E1**, **E4**, **E8**, **E12**, **H1**, **H4**, **H8**, and **H12**.
3. Place the 9600 Temperature Verification Frame on the sample block with the channel facing the front of the instrument.
4. Place the 0.2-mL Probe Assembly into well **A1**.
5. Thread the probe wire through the channel in the 9600 Temperature Verification Frame to prevent damage to the probe and lead wires. Make sure the probe is connected to the digital thermometer. (See Figure 4-1 on page 4-2.)

6. Slide the heated cover forward, then turn the cover knob clockwise until the white mark on the knob is aligned with the white mark on the cover.

   IMPORTANT! The probe must be seated properly and the heated cover closed carefully. If the probe wire is crushed when the heated cover is closed, the probe can be damaged.

7. Turn on the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

Running the Test

To run the Temperature Non-Uniformity Test:

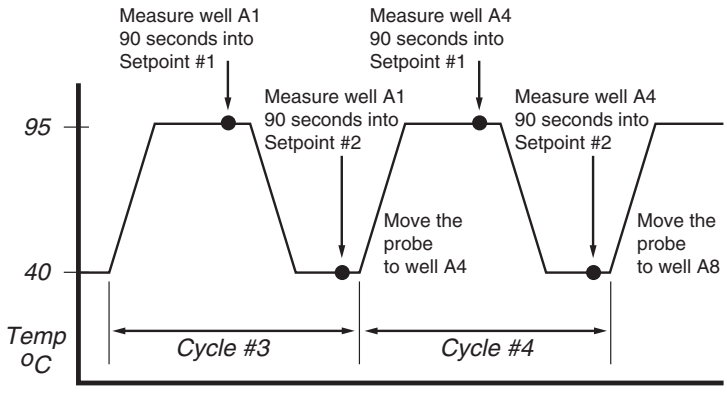
1. Start up the system 9600 and set up a two-temperature CYCL program with the following parameters:
   - Setpoint #1 Temperature = 95 °C
   - Hold Time = 2:00 minutes
   - Ramp Time = 0:00 minutes
   - Setpoint #2 Temperature = 40 °C
   - Hold Time = 2:00 minutes
   - Ramp Time = 0:00 minutes
   - Cycles = 99

   Note: Refer to *GeneAmp® PCR System 9600 User's Manual* (P/N 0093-8660) for details on how to set up a CYCL program.

2. On the third cycle, measure the temperature of well **A1** 90 seconds into Setpoint #1 (95 °C setpoint temperature) using the digital thermometer. The time-remaining clock on the run-time display will read "0:30" (30 seconds). Record this temperature.

3. Again on the third cycle, measure the temperature of well **A1** 90 seconds into Setpoint #2 (40 °C setpoint temperature) using the digital thermometer. The time-remaining clock on the run-time display will read "0:30" (30 seconds). Record this temperature.

   The figure below shows when to measure the temperatures.



4. After you measure the second temperature of well A1, turn the cover knob completely counterclockwise, then slide the heater cover back.

5. Move the probe assembly to the next well to be measured.
6. Slide the heater cover forward, then turn the cover knob clockwise until the white mark on the knob and the white mark on the cover are aligned.
7. Repeat the measurements on wells **A4**, **A8**, **A12**, **C1**, **C4**, **C8**, **C12**, **E1**, **E4**, **E8**, **E12**, **H1**, **H4**, **H8**, **H12**.

   Note: The temperature display on the digital thermometer may not match the temperature display on the system 9600 because the heated sample block cover affects the probe temperature. If you suspect any temperature calibration problems, perform the Calibration Verification Test described on page 4-3.

Calculating Test Results

Use the following information to calculate the results of the test.

Note: If there is more than one system 9600 in your laboratory, verify that the serial number on the calibration label matches the serial number on the instrument you are testing.

For the 16 Setpoint #1 measurements (95 °C hold), subtract the lowest measured temperature from the highest measured temperature.

For the 16 Setpoint #2 measurements (40 °C hold), subtract the lowest measured temperature from the highest measured temperature.

If either result is greater than 1 °C, your GeneAmp PCR System 9600 must be serviced by an Applied Biosystems service representative.

Ending the Test

To end the test:

1. Remove the 0.2-mL Probe Assembly from the sample block.
2. Power off the digital thermometer and clean off the oil.
3. Wait for the sample block to reach room temperature (~25 °C), then remove the 9600 Temperature Verification Frame from the sample block.

   PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.
4. Clean the oil off the sample block.

Data Sheet: Calibration Verification Test

When you run the Calibration Verification Test, record the setpoint values for well **E1** on this data sheet. At the end of the Calibration Verification Test, check the values displayed on the system 9600 against the values recorded here.

Note: You can photocopy this page.

Date	Tested By	Probe Serial No.	Thermometer Serial No.	Setpoint Value: Well E1	
				95 °C	40 °C

Data Sheet: Temperature Non-Uniformity Test

When you run the Temperature Non-Uniformity Test, record the setpoint values for the wells listed on this data sheet. At the end of the Temperature Non-Uniformity Test, check the values displayed on the system 9600 against the values recorded here.

Note: You can photocopy this page.

Date		
Tested By		
Probe Serial No.		
Thermometer Serial No.		
Setpoint Value	**95 °C**	**40 °C**
A1		
A4		
A8		
A12		
C1		
C4		
C8		
C12		
E1		
E4		
E8		
E12		
H1		
H4		
H8		
H12		

Temperature Verification Tests for the System 2400

5

This chapter covers:

Overview

Materials

When you perform temperature verification tests on the System 2400, you use the materials provided in your kit.

Assembly

Figure 5-1 shows a properly assembled system. Note that the frame is positioned around the wells with the channel facing you, and the probe wire is threaded through the channel to prevent damaging the wire when the thermal cycler's heated cover is closed.

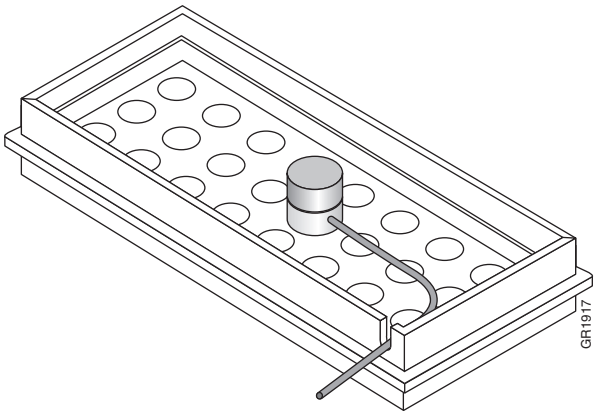


Figure 5-1 Proper assembly of the Temperature Verification System for System 2400

Calibration Verification Test

Overview

Use this test to verify the temperature calibration of your system 2400.

The Calibration Verification Test consists of the following subprocedures, which must be done in order:

PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.

Required Materials

This test requires the 0.2-mL Temperature Verification Kit (PN 4317939), which includes:

- Cotton swabs
- Light mineral oil
- 2400 Temperature Verification Frame
- 0.2-mL Probe Assembly
- Model 4500 digital thermometer with 9V battery installed

Setting Up the 0.2-mL Probe Assembly

To set up the 0.2-mL Probe Assembly

1. If the heated cover is in the forward position, lift the lever, then slide the heated cover back.
2. Place the 2400 Temperature Verification Frame on the sample block.
3. Using a cotton swab, coat well **B4** with mineral oil.
4. Place the 0.2-mL Probe Assembly into well **B4**.
5. Thread the probe wire through the channel in the 2400 Temperature Verification Frame to prevent damage to the probe and lead wires. (See Figure 5-1 on page 5-2.)
6. Make sure the probe is connected to the digital thermometer.

7. Slide the heated cover forward and pull the lever down.

   IMPORTANT! The probe must be seated properly and the heated cover closed carefully. If the probe wire is crushed when the heated cover is closed, the probe can be damaged.

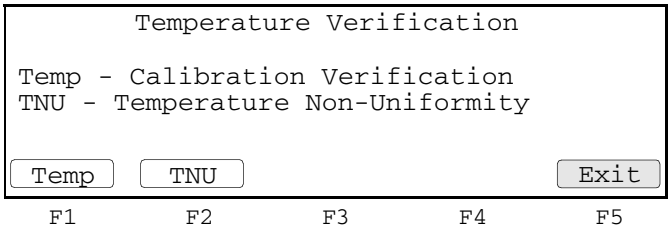
8. Power on the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

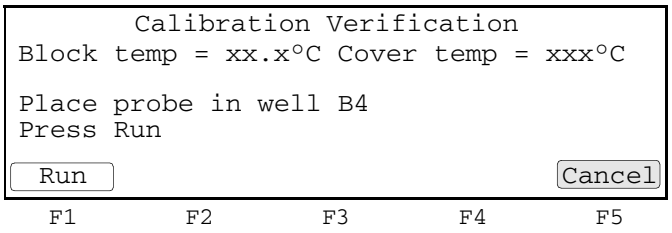
Configuring the System 2400

To configure the system 2400:

1. Start up the system 2400. The Main menu appears.
2. Press **F4** (Util)**.** The Utilities screen appears.
3. Press **F1** (Diag). The Diagnostics screen appears.
4. Press **F3** (TmpVer). The Temperature Verification screen appears.



5. Press **F1** (Temp). The system 2400 is automatically configured for the Calibration Verification Test, and the Calibration Verification screen appears.



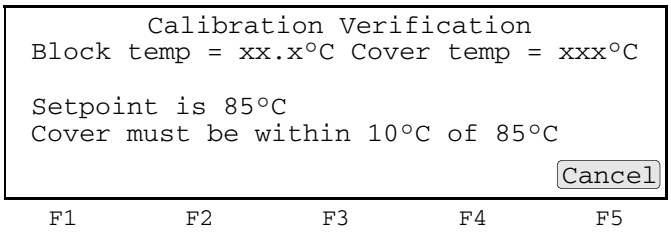
Running the Test

In this test, you take temperature readings of the sample well at two different setpoint temperatures using the 0.2-mL Probe Assembly..

Note: Press **F5** (Cancel) if you want to exit the test.

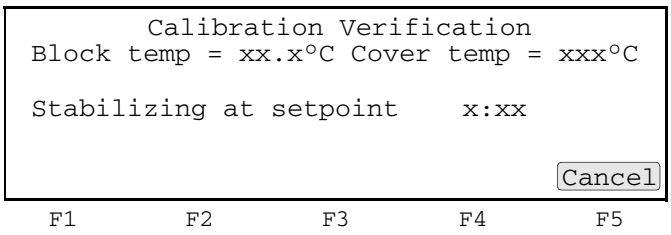
To run the Calibration Verification Test:

1. Press **F1** (Run). The Calibration Verification Test starts, and the Calibration Verification screen appears with the setpoint value displayed.



Note: The cover must be at 105 °C ±1 °C. It may take several minutes for the system 2400 to ramp up.

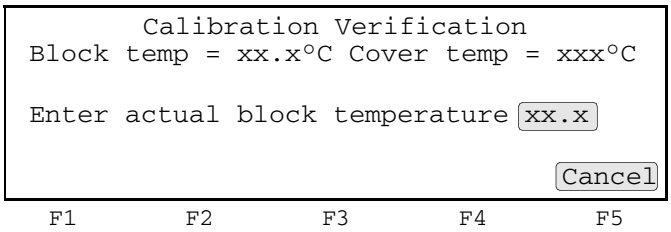
The Calibration Verification screen counts down the time until the setpoint is reached.



2. When the "Stabilizing at setpoint" value decreases to 0, read the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

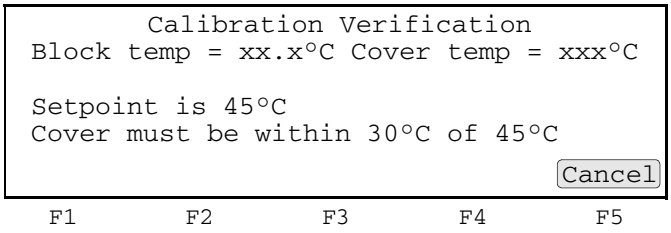
3. Using the numeric keys, type the value displayed on the digital thermometer in the "Enter actual block temperature" field.



   Note: The digital thermometer displays a four-digit value; round this off to three digits before typing it in the Calibration Verification screen.

   Note: Record this value on the Calibration Verification Test Data Sheet (page 5-13) to keep a permanent record of the test.

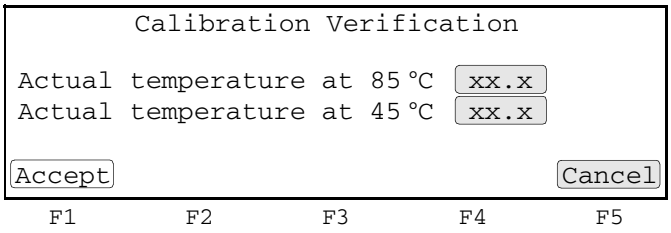
4. Press **Enter**. The system 2400 automatically begins the second reading (45 °C setpoint), and the Calibration Verification screen appears with the setpoint value displayed.



Note: The cover must be at 105 °C ±1 °C . It may take several minutes for the system to ramp up.

5. Repeat steps 2 through 4 for the second reading.

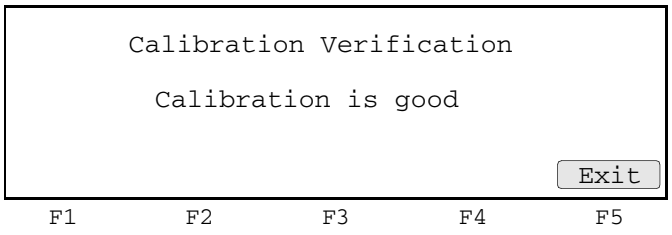
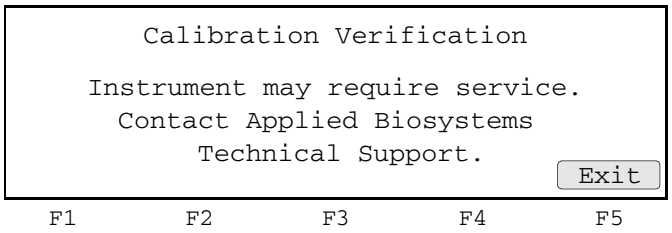
   The system 2400 evaluates the calibration of the sample block temperature for the setpoint values you entered and displays the results. A summary screen appears at the conclusion of the test.



6. If you entered values on the Calibration Verification Test Data Sheet (page 5-13), compare those values with the actual test results.
7. Press **F1** (Accept).

Evaluating the Results

After the system 2400 completes the Calibration Verification Test, one of two screens appears, depending on the test results. See the table below to evaluate the results.

If the sample block module...	Then the...
Is properly calibrated	Calibration Verification screen appears with the following message displayed. 
Does not pass the Calibration Verification Test	Calibration Verification screen appears with the following message displayed.  • If the test fails, repeat the procedure to make sure the digital thermometer was not misread or that data entry errors were not made. • If the test fails again, contact Applied Biosystems Technical Support.

Ending the Test

To end the test:

1. Press **F5** (Exit).
2. Remove the 0.2-mL Probe Assembly from the sample block.
3. Power off the digital thermometer and clean off the oil.
4. Wait for the sample block to reach room temperature (~25 °C), then remove the 2400 Temperature Verification Frame from the sample block.

   WARNING **PHYSICAL INJURY HAZARD.** Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.
5. Clean the oil off the sample block.

Temperature Non-Uniformity Test

Overview

Use this test to verify the temperature uniformity of the system 2400.

The Temperature Non-Uniformity Test consists of the following subprocedures, which must be done in order:

WARNING **PHYSICAL INJURY HAZARD.** Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.

Equipment Required

This test requires the 0.2-mL Temperature Verification Kit (PN 4317939), which includes:

- Cotton swabs
- Light mineral oil
- 2400 Temperature Verification Frame
- 0.2-mL Probe Assembly
- Model 4500 digital thermometer with 9V battery installed

Setting Up the 0.2-mL Probe Assembly

To set up the 0.2-mL Probe Assembly:

1. If the heated cover is in the forward position, lift the lever, then slide the heated cover back.
2. Place the 2400 Temperature Verification Frame on the sample block.
3. Using a cotton swab, coat the following wells with mineral oil: **A2**, **A7**, **B1**, **B4**, **B8**, **C2**, and **C7**.
4. Place the 0.2-mL Probe Assembly into well **A2**.

   Note: As the test progresses, you move the 0.2-mL Probe Assembly to each of the test wells.
5. Thread the probe wire through the channel in the 2400 Temperature Verification Frame to prevent damage to the probe and lead wires. (See Figure 5-1 on page 5-2.)
6. Make sure the probe is connected to the digital thermometer.

7. Slide the heated cover forward and pull the lever down.

   IMPORTANT! Seat the probe properly and close the heated cover carefully. If the probe wire is crushed when the heated cover is closed, the probe can be damaged.

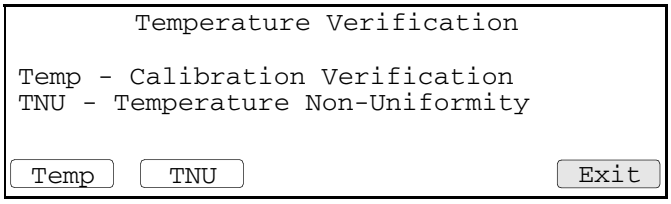
8. Power on the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

Configuring the System 2400

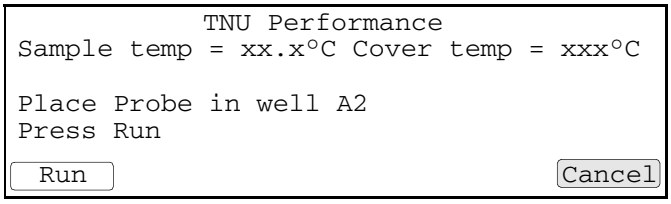
To configure the system 2400:

1. Start up the system 2400. The Main menu appears.
2. Press **F4** (Util)**.** The Utilities screen appears.
3. Press **F1** (Diag). The Diagnostics screen appears.
4. Press **F3** (TmpVer). The Temperature Verification screen appears.



5. Press **F2** (TNU).

   The system 2400 is automatically configured for the Temperature Non-Uniformity Test, and the TNU Performance screen appears.



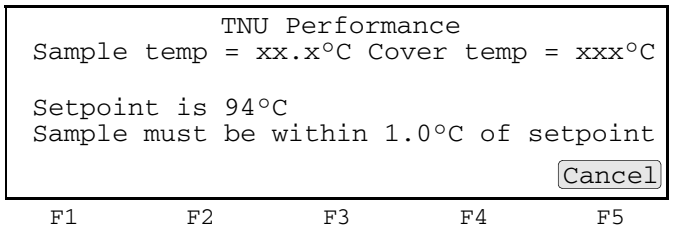
Running the Test

The Temperature Non-Uniformity Test uses the 0.2-mL Probe Assembly to test the temperature uniformity of 7 different wells in the sample block.

Note: Press **F5** (Cancel) if you want to exit the test.

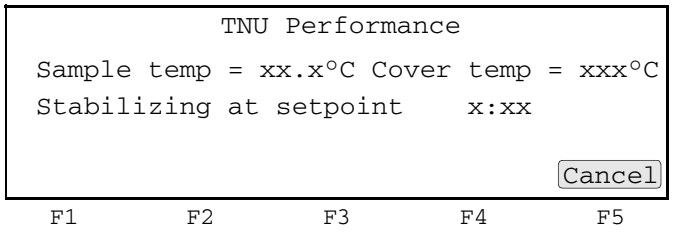
To run the Temperature Non-Uniformity Test:

1. Press **F1** (Run). The Temperature Non-Uniformity Test starts, and the TNU Performance screen appears with the setpoint value displayed.



Note: The sample block must be at 94 °C ±1.0 °C. In addition, the cover must be at 105 °C ±1 °C. It may take several minutes for the system 2400 to ramp up.

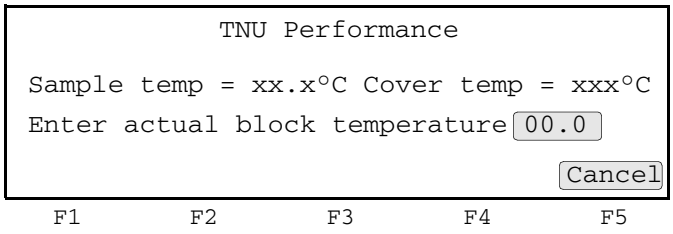
The TNU Performance screen counts down the time until the setpoint is stabilized.



2. When the "Stabilizing at setpoint" value decreases to 0, read the digital thermometer.

   Note: Refer to the instructions included with your Temperature Verification Kit for details on operating the Model 4500 digital thermometer.

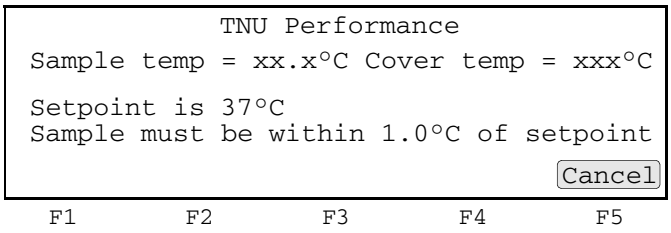
3. Using the numeric keys, type the value displayed on the digital thermometer in the "Enter actual block temperature" field.



   Note: The digital thermometer displays a four-digit value; round this off to three digits before typing it in the TNU Performance screen.

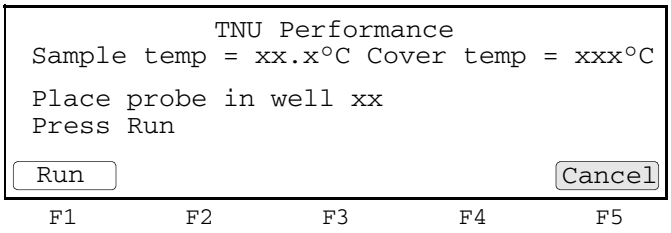
   Note: Record this value on the Temperature Non-Uniformity Test Data Sheet (page 5-14) to keep a permanent record of the test.

4. Press **Enter**. The system 2400 automatically begins the second reading (37 °C setpoint), and TNU Performance screen appears with the setpoint value displayed.



Note: The sample block must be at 34 °C ±1.0 °C.

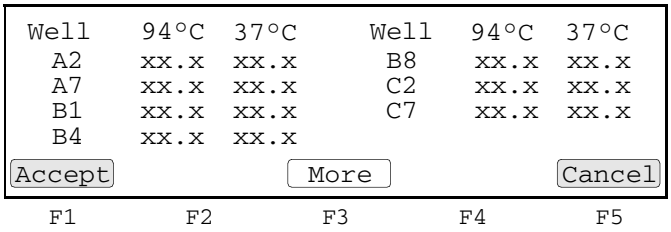
5. Repeat steps 2 through 4 for the second reading.
6. Press **Enter**. The TNU Performance screen appears with the following prompt:



7. Slide the heated cover back and repeat steps 4 through 7 of "Setting Up the 0.2-mL Probe Assembly" on page 5-8 and steps 1 through 6 of this procedure.

   Complete these steps for the remaining 6 wells to be tested:
   A7, **B1**, **B4**, **B8**, **C2**, and **C7**.

8. The system 2400 evaluates the uniformity of the sample block temperature for the setpoint values you entered and displays the results. A summary screen appears at the conclusion of the test.

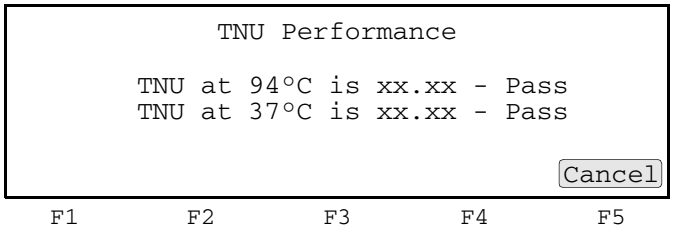
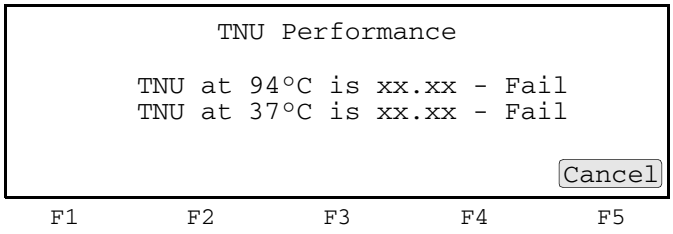


   If you entered values on the Temperature Non-Uniformity Test Data Sheet (page 5-14), compare those values with the actual test results.

9. Press **F1** (Accept).

Evaluating the Results

After the system 2400 completes the Temperature Non-Uniformity Test, the TNU Performance screen appears. See the table below to evaluate the results.

If the...	Then...
Temperature of the sample block wells is uniform,	"Pass" appears after each setpoint temperature. 
Temperature variation of the sample block wells exceeds performance specifications,	"Fail" appears after the setpoint temperature(s) for which the test failed.  • If the test fails, repeat the procedure to make sure the digital thermometer was not misread or that data entry errors were not made. • If the test fails again, contact Applied Biosystems Technical Support.

Ending the Test

To end the test:

1. Press **F5** (Cancel).
2. Remove the 0.2-mL Probe Assembly from the sample block.
3. Power off the digital thermometer and clean off the oil.
4. Wait for the sample block to reach room temperature (~25 °C), then remove the 2400 Temperature Verification Frame from the sample block.

   WARNING **PHYSICAL INJURY HAZARD.** Hot Surface. Use care when working around the heated cover and sample block to avoid being burned by hot components.
5. Clean the oil off the sample block.

Data Sheet: Calibration Verification Test

When you run the Calibration Verification Test, record the setpoint values for well **B4** on this data sheet. At the end of the Calibration Verification Test, check the values displayed on the system 2400 against the values recorded here.

Note: You can photocopy this page.

Date	Tested By	Probe Serial No.	Thermometer Serial No.	Setpoint Value: Well B4	
				85 °C	45 °C

Data Sheet: Temperature Non-Uniformity Test

When you run the Temperature Non-Uniformity Test, record the setpoint values for the wells listed on this data sheet. At the end of the Temperature Non-Uniformity Test, check the values displayed on the system 2400 against the values recorded here.

Note: You can photocopy this page.

Date		
Tested By		
Probe Serial No.		
Thermometer Serial No.		
Setpoint Value	**94 °C**	**37 °C**
A2		
A7		
B1		
B4		
B8		
C2		
C7		

Recalibration A

This appendix describes how to obtain recalibration service for your Temperature Verification System.

Obtaining Recalibration

Introduction

Applied Biosystems recommends that the Model 4500 digital thermometer and 0.2-mL Probe Assembly be recalibrated on an annual basis.

To have your thermometer and probe recalibrated:

1. Decontaminate the probe assembly, as described below.
2. Send the equipment to the manufacturer, as described below.

Decontaminating the Probe Assembly

To decontaminate the probe assembly:

1. Gently wipe the probe cone with a cotton swab that has been moistened with bleach solution (20% bleach, 80% water).

   IMPORTANT! Do not submerge the probe in bleach solution. Do not disassemble the probe assembly.

   ⚠ WARNING CHEMICAL HAZARD. Sodium hypochlorite (bleach) is a liquid disinfectant that can be corrosive to the skin and can cause skin depigmentation. Please read the MSDS, and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves.

2. Complete a Decontamination Certificate. See Appendix C, "Certificate of Decontamination."

Sending Equipment to Alpha Technics

To send your equipment for recalibration:

1. Inform Alpha Technics of the recalibration order by either of the following methods:
   - Mail the purchase order directly to:
     Alpha Technics
     1560 Orangethorpe Way
     Anaheim, CA 92801

     or
   - Faxthe purchase order directly to Alpha Technics (714) 773-9327
2. Ensure that the probe assembly has been decontaminated.
3. Pack the Model 4500 digital thermometer and 0.2-mL Probe Assembly in the black case, then send to the address above.

4. Create a package with:
   - Black case containing digital thermometer and probe assembly
   - Decontamination certificate (see Appendix C).
   - Payment of $135.00 plus $15.00 for shipping/handling:
     - purchase order, or
     - company letterhead with the words “verbal purchase order,” or
     - Visa/MasterCard credit card information
   - Address and contact information:
     - billing address
     - shipping address
     - name and phone number of a contact (person most familiar with the thermometer)

   Note: If payment is not included with the package, Alpha Technics bills you for the amount of $150.00 plus a 10% administrative fee. The total for the purchase order is then $165.00.

5. Send the package freight prepaid to Alpha Technics at the address shown in step 1.

Instrument Warranty Information B

This appendix contains the following:

Computer Configuration

Applied Biosystems supplies or recommends certain configurations of computer hardware, software, and peripherals for use with its instrumentation.
Applied Biosystems reserves the right to decline support for or impose extra charges for supporting nonstandard computer configurations or components that have not been supplied or recommended by Applied Biosystems. Applied Biosystems also reserves the right to require that computer hardware and software be restored to the standard configuration prior to providing service or technical support. For systems that have built-in computers or processing units, installing unauthorized hardware or software may void the Warranty or Service Plan.

Limited Product Warranty

Limited Warranty

Applied Biosystems warrants that all standard components of its Thermal Cycler Temperature Verification System for GeneAmp® PCR Systems with a 0.2-mL Sample Block will be free of defects in materials and workmanship for a period of one (1) year from the date the warranty period begins. Applied Biosystems will repair or replace, at its discretion, all defective components during this warranty period. After this warranty period, repairs and replacement components may be purchased from Applied Biosystems at its published rates. Applied Biosystems also provides service agreements for post-warranty coverage. Applied Biosystems reserves the right to use new, repaired, or refurbished instruments or components for warranty and post-warranty service agreement replacements. Repair or replacement of products or components that are under warranty does not extend the original warranty period.

Applied Biosystems warrants that all optional accessories supplied with its Thermal Cycler Temperature Verification System for GeneAmp PCR Systems with a 0.2-mL Sample Block, such as peripherals, printers, and special monitors, will be free of defects in materials and workmanship for a period of ninety (90) days from the date the warranty begins. Applied Biosystems will repair or replace, at its discretion, defective accessories during this warranty period. After this warranty period, Applied Biosystems will pass on to the buyer, to the extent that it is permitted to do so, the warranty of the original manufacturer for such accessories.

With the exception of consumable and maintenance items, replaceable products or components used on or in the instrument are themselves warranted to be free of defects in materials and workmanship for a period of ninety (90) days.

Applied Biosystems warrants that chemicals and other consumable products will be free of defects in materials and workmanship when received by the buyer, but not thereafter, unless otherwise specified in documentation accompanying the product.

Applied Biosystems warrants that for a period of ninety (90) days from the date the warranty period begins, the tapes, diskettes, or other media bearing the operating software of the product, if any, will be free of defects in materials and workmanship under normal use. If there is a defect in the media covered by the above warranty and the media is returned to Applied Biosystems within the ninety (90) day warranty period, Applied Biosystems will replace the defective media.

Applied Biosystems does not warrant that the operation of the instrument or its operating software will be uninterrupted or error free.

Warranty Period Effective Date

Any applicable warranty period under these sections begins on the earlier of the date of installation or ninety (90) days from the date of shipment for hardware and software installed by Applied Biosystems personnel. For all hardware and software installed by the buyer or anyone other than Applied Biosystems, and for all other products, the applicable warranty period begins the date the product is delivered to the buyer.

Warranty Claims

Warranty claims must be made within the applicable warranty period, or, for chemicals or other consumable products, within thirty (30) days after receipt by the buyer.

Warranty Exceptions

The above warranties do not apply to defects resulting from misuse, neglect, or accident, including without limitation: operation with incompatible solvents or samples in the system; operation outside of the environmental or use specifications or not in conformance with the instructions for the instrument system, software, or accessories; improper or inadequate maintenance by the user; installation of software or interfacing, or use in combination with software or products, not supplied or authorized by Applied Biosystems; and modification or repair of the product not authorized by Applied Biosystems.

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Warranty Limitations

THE REMEDIES PROVIDED HEREIN ARE THE BUYER'S SOLE AND EXCLUSIVE REMEDIES. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, IN NO EVENT SHALL APPLIED BIOSYSTEMS BE LIABLE, WHETHER IN CONTRACT, TORT, WARRANTY, OR UNDER ANY STATUTE (INCLUDING WITHOUT LIMITATION, ANY TRADE PRACTICE, UNFAIR COMPETITION, OR OTHER STATUTE OF SIMILAR IMPORT) OR ON ANY OTHER BASIS, FOR DIRECT, INDIRECT, PUNITIVE, INCIDENTAL, MULTIPLE, CONSEQUENTIAL, OR SPECIAL DAMAGES SUSTAINED BY THE BUYER OR ANY OTHER PERSON OR ENTITY, WHETHER OR NOT FORESEEABLE AND WHETHER OR NOT APPLIED BIOSYSTEMS IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, INCLUDING WITHOUT LIMITATION, DAMAGES ARISING FROM OR RELATED TO LOSS OF USE, LOSS OF DATA, FAILURE OR INTERRUPTION IN THE OPERATION OF ANY EQUIPMENT OR SOFTWARE, DELAY IN REPAIR OR REPLACEMENT, OR FOR LOSS OF REVENUE OR PROFITS, LOSS OF GOOD WILL, LOSS OF BUSINESS, OR OTHER FINANCIAL LOSS OR PERSONAL INJURY OR PROPERTY DAMAGE.

NO AGENT, EMPLOYEE, OR REPRESENTATIVE OF APPLIED BIOSYSTEMS HAS ANY AUTHORITY TO MODIFY THE TERMS OF THIS LIMITED WARRANTY STATEMENT OR TO BIND APPLIED BIOSYSTEMS TO ANY AFFIRMATION, REPRESENTATION, OR WARRANTY CONCERNING THE PRODUCT THAT IS NOT

CONTAINED IN THIS LIMITED WARRANTY STATEMENT, AND ANY SUCH MODIFICATION, AFFIRMATION, REPRESENTATION, OR WARRANTY MADE BY ANY AGENT, EMPLOYEE, OR REPRESENTATIVE OF APPLIED BIOSYSTEMS WILL NOT BE BINDING ON APPLIED BIOSYSTEMS, UNLESS IN A WRITING SIGNED BY AN EXECUTIVE OFFICER OF APPLIED BIOSYSTEMS.

THIS WARRANTY IS LIMITED TO THE BUYER OF THE PRODUCT FROM APPLIED BIOSYSTEMS AND IS NOT TRANSFERABLE.

Some countries or jurisdictions limit the scope of or preclude limitations or exclusion of warranties, of liability, such as liability for gross negligence or wilful misconduct, or of remedies or damages, as or to the extent set forth above. In such countries and jurisdictions, the limitation or exclusion of warranties, liability, remedies or damages set forth above shall apply to the fullest extent permitted by law, and shall not apply to the extent prohibited by law.

Damages, Claims, and Returns

Damages

If shipping damage to the product is discovered, contact the shipping carrier and request inspection by a local agent. Secure a written report of the findings to support any claim. Do not return damaged goods to Applied Biosystems without first securing an inspection report and contacting Applied Biosystems Technical Support for a Return Authorization (RA) number.

Claims

After a damage inspection report is received by Applied Biosystems, Applied Biosystems will process the claim unless other instructions are provided.

Returns

Do not return any material without prior notification and authorization.

If for any reason it becomes necessary to return material to Applied Biosystems, contact Applied Biosystems Technical Support or your nearest Applied Biosystems subsidiary or distributor for a return authorization (RA) number and forwarding address. Place the RA number in a prominent location on the outside of the shipping container, and return the material to the address designated by the Applied Biosystems representative.

Certificate of Decontamination C

The following form is supplied to you for the purpose of shipping your instrument to Applied Biosystems for repair or service, and/or prior to any on-site service to be performed by Applied Biosystems.

A completed copy of the Certificate of Decontamination must be attached to the instrument or part itself, and a copy of this certificate must be attached to the outside of the packing container when transporting to an Applied Biosystems facility.

Print out and enter the requested information as appropriate.

Applied Biosystems

CERTIFICATE OF DECONTAMINATION

This document must be completed in full and signed by the Customer (a) before transporting, by any means, a product to Applied Biosystems for repair or service, and (b) prior to any on-site service to be performed by Applied Biosystems.

A completed copy of this Certificate is required to be attached to the instrument / part itself AND to the outside of the packing container when transporting to an Applied Biosystems Facility.

SUPPLY THE FOLLOWING INFORMATION ABOUT THE APPLIED BIOSYSTEMS PRODUCT.
(Examples of Decontamination Procedures are described on the back of this sheet)

Instrument Model/Type OR Part Name: _____
Instrument or Part Serial Number: _____
Reason for return/service: _____
RMA or RA number (required if product is to be returned to Applied Biosystems): _____
Field Service Engineer Name (if applicable): _____

Has this product been used? **YES** ☐ **NO** ☐

If YES, the next question should be checked "YES" with all supporting information provided.
If NO, then this product was received non functioning and/or NO buffers, reagents, chemicals, or samples of any nature were used with or on this product.

Has this product been exposed to any buffers, reagents, and/or chemicals? **YES** ☐ **NO** ☐

Chemicals include but are not limited to: carcinogens, sensitizers, mutagens, teratogens, and toxics. Determine classification of chemical from chemical label or MSDS.

If YES, list all buffers, reagents, and/or chemicals used on or with this product: (Attach additional sheet if necessary)_____
_____

If YES, describe the procedures used to decontaminate the product of the identified buffers, reagents, and/or chemicals: (Attach additional sheet if necessary)_____
_____

Has this product been exposed to any radioactive substances? **YES** ☐ **NO** ☐

If YES, which radioactive isotopes: (Attach separate sheet if necessary)_____

If YES, describe the procedures used to decontaminate the product of the identified radioactive substances: (Attach additional sheet if necessary). Customer agrees that products will not be shipped until all radioactivity has been removed. _____
_____

Has this product been exposed to infectious agents? **YES** ☐ **NO** ☐

If YES, which infectious agent(s)? Which Biosafety Levels? (as defined in the 4th Edition, Biosafety in Microbiological and Biomedical Laboratories, USDHHS, CDC, NIH)? (Attach separate sheet if necessary)
_____

If YES, describe all the procedures used to decontaminate the product of the identified infectious agents: (Attach additional sheet necessary)_____
_____

The Customer understands and agrees that decontamination is critical to issues of health and safety and that thoroughly completing this Certificate is essential. Customer represents and warrants to Applied Biosystems that it performed all decontamination procedures as described in this Certificate and completed this Certificate accurately, truthfully, and in full. Customer hereby assumes all responsibility and liability for and shall defend and indemnify Applied Biosystems against, injury or damage of whatever kind incurred by Applied Biosystems, its employees, contractors, and/or agents that result directly or indirectly from Customer's breach of this representation and warranty. The Customer accepts that Applied Biosystems has no obligation to repair, service, or transport any product if this Certificate is not completed in full.

Company: _____ **Date:** _____
(Print Name)

By Signature: _____ **Print Name:** _____ **Phone:**_____

AB Part Number: 4343055
Rev. B

Examples of Decontamination Procedures

The following are widely used industry standards for decontamination.

For Chemical (buffers, reagents, carcinogens, toxins, sensitizers, teratogens, and mutagens) Contaminants

1. Rinse areas associated with chemicals with an acceptable solvent such as methyl alcohol, ethyl alcohol, or isopropyl alcohol.
2. Then rinse with detergent and water.

For Radioactive Materials

1. Apply an industry standard r adioactivity decontaminant (e.g. Radiacwash®, Rad-Con®) or equivalent to product surfaces and wipe surfaces as directed by decontaminant manufacturer.
2. Survey the product with appropriate radioactivity measuring instrument (e.g. Geiger Counter or scintillation counter) and attach the results to this form.
3. Satisfactory decontamination is defined as survey results at or below local background levels.
4. Repeat steps 1 and 2 until achieving satisfactory survey results.

For Infectious Agents – Customer will evaluate and determine type of decontamination required.

1. For Products used only with Risk Group 1 Non Pathogenic Agents, reagents, buffers, and chemicals that have Material Safety Data Sheets. Products that have NOT been exposed to any human source mate rial or cell culture including clinical samples.
2. This classification of product does not require infectious agent decontamination. This product may require chemical decontamination depending on what chemicals were used on this product.
3. For Products used with any Risk Group 2 Agents or products that HAVE BEEN exposed to any human source material or cell culture including clinical samples.
   c. If your product requires decontamination by an outside service as defined by your User Manual or Applied Biosystems Representative, follow all directions for that method of decontamination.
   d. Otherwise:
      i. Apply a freshly made solution of 1:10 v/v dilution of 5.25% sodium hypochlorite (e.g. Clorox bleach) with water to applicable product surfaces. Follow Universal Precautions and wear all applicable personal protective equipment (e.g. labcoat, gloves, etc.) at all times while handling the product.
      ii. Place product in a well ventilated area. Apply freshly prepared 10% aqueous solution of bleach.
      iii. Maintain surfaces in wet condition for 15 minutes. A spray bottle may be used to carefully apply this solution.
      iv. After 15 minutes wipe dry.
      v. Repeat application of prepared solution and maintain in wet condition for an additional 15 minutes, and again wipe dry.
      vi. As a final step, w ipe down all decontaminated surfaces with clear water to remove residual bleach.
   e. An alternative solution may be used if the Customer can provide information indicating that the alternative is as effective as 1:10 dilution household bleach solution. Documentation for this shall be provided in written form and attached to the Certificate of Decontamination.
4. For Products used with Risk Group 3 or 4 Agents or housed in a Biosafety Level 3 or Biosafety Level 4 Laboratory.
   a. Decontamination of Applied Biosystems' Products used with Risk Group 3 or 4 or housed in a Biosafety Level 3 or 4 Laboratory must be discussed with and approved by Applied Biosystems' Environmental, Health, and Safety Representative. It may not be possible for Applied Biosystems to service or transport these products.
      i. Environmental, Health, and Safety US Western Region Phone: (650) 638-5088
      ii. Environmental, Health, and Safety US Eastern Region Phone: (508) 383-7835
      iii. Environmental, Health, and Safety Europe and Asia Phone: 011-44-1793-829146

For the Valve Block

1. Flush the valve block and dry with an appropriate gas: Argon, Helium, or Nitrogen.
2. If the valve block is constricted and not able to be flushed properly, remove the valve block and label it as a "Hazardous Waste Solid" and dispose in accordance with all local, State, Federal Environmental laws and regulations.

Other

Should an alternative decontamination procedure be performed, the Customer shall document the procedure in detail. The documentation shall be included with the Certificate of Decontamination as supporting data.

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