Applied Biosystems
9800 FAST Thermal Cycler

Installation Qualification and Operation Qualification Protocol

Instrument Serial Numbers

Base Module: _____

Sample Block Module: _____

Protocol Execution Date _____

Applied Biosystems

Information in this Installation Qualification/Operation Qualification Protocol ("IQ/OQ Protocol") for the Applied Biosystems 9800 Fast Thermal Cycler is subject to change without notice. No changes will be made to this IQ/OQ Protocol during its execution without the consent of Applied Biosystems ("AB") and the customer. AB assumes no responsibility for any errors that may appear in this document.

THIS DOCUMENT IS PROVIDED AS IS. APPLIED BIOSYSTEMS DISCLAIMS ALL WARRANTIES WITH RESPECT TO THESE INSTALLATION QUALIFICATION AND OPERATION QUALIFICATION SERVICES AND THIS IQ/OQ PROTOCOL, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO THOSE OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

IN NO EVENT SHALL APPLIED BIOSYSTEMS BE LIABLE, WHETHER IN CONTRACT, TORT, WARRANTY, OR UNDER ANY STATUTE OR ON ANY OTHER BASIS FOR SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE, MULTIPLE OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH OR ARISING FROM APPLIED BIOSYSTEMS' PRODUCTS AND SERVICES OR THE USE OF THIS DOCUMENT.

Printed in the USA, 12/2006
Part Number *4374845*, Revision C

IQ/OQ PROTOCOL
TABLE OF CONTENTS

1 Installation Qualification/Operation Qualification (IQ/OQ) Protocol Pre-Approval

1.1 Review and approve this IQ/OQ Protocol according to the procedures and quality system requirements of the organization that owns the instrument. At a minimum, the instrument owner and the owner's quality department must sign (in ink) below.

1.2 Approve the IQ/OQ Protocol prior to performing the protocol by completing the approvals below. Add more signatures as required. Fill in any blank spaces below with "N/A," indicating "Not Applicable." Other departments affected by the outcome of the IQ/OQ process are recommended to review and approve this IQ/OQ Protocol.

1.3 The completion of the approvals below indicates that the Applied Biosystems 9800 FAST Thermal Cycler IQ/OQ Protocol:

- Has been reviewed and approved by the instrument owner and the quality representative of the organization that owns the instrument
- Is ready to be performed.

Pre-Approval:

Print Name	Signature	Title	Date
Print Name	Signature	Title	Date
Print Name	Signature	Title	Date
Print Name	Signature	Title	Date
Print Name	Signature	Title	Date
Print Name	Signature	Title	Date

2 Introduction

2.1 This IQ/OQ Protocol is used to verify:

- The initial installation and operation of an Applied Biosystems 9800 FAST Thermal Cycler.
- A pre-verified Applied Biosystems 9800 FAST Thermal Cycler that has been reinstalled or moved to a new location.

This protocol is designed to be followed in sequence, from beginning to end.

2.2 Successful completion of this IQ/OQ Protocol verifies the Applied Biosystems 9800 FAST Thermal Cycler is, at the time of testing, installed and operating in accordance with Applied Biosystems specifications, with any exceptions noted.

2.3 Any exception conditions that occur during the performance of this IQ/OQ Protocol shall be identified for review. Exception conditions will be investigated and the appropriate course of action determined. The operator identified by the owner of the instrument will be responsible for the successful execution and completion of the IQ/OQ Protocol.

2.4 To verify an Applied Biosystems 9800 FAST Thermal Cycler that has previously been verified using an Applied Biosystems IQ/OQ Protocol, but has subsequently undergone service, repair, or maintenance that is critical to the performance of the Applied Biosystems 9800 FAST Thermal Cycler, or has site requirements for a scheduled operation qualification, use an *Applied Biosystems 9800 FAST Thermal Cycler Instrument Performance Verification Protocol* (ordered separately from Applied Biosystems) instead of this IQ/OQ Protocol. See Section 8 for more information about when to perform an Applied Biosystems 9800 FAST Thermal Cycler IPV Protocol.

3 Purpose

The purpose of this IQ/OQ Protocol is to verify and record, at the time of testing that the Applied Biosystems 9800 FAST Thermal Cycler is installed and operating in accordance with the Applied Biosystems installation and operation specifications described in this Protocol, and that such tests confirm that the Applied Biosystems 9800 FAST Thermal Cycler is installed and at the time of testing operates in accordance with Applied Biosystems' specifications set forth in the PCR System User's Manuals:

- 9800 Fast Thermal Cycler Base Module User Guide (PN 4350088)
- 9800 Fast Thermal Cycler with 96-Well Aluminum Sample Block Module (PN 4350087)
- CD,FAST Thermal Cycler 9800 (PN 4350542)

The performance of this IQ/OQ Protocol results in an IQ/OQ documentation package that includes completed Verification Data Sheets and identified attachments.

4 Scope

4.1 The Applied Biosystems 9800 FAST Thermal Cycler, including consumables and core instrument software associated with routine operation, data collection, analysis and reporting, is qualified as part of the operational qualification of this system.

4.2 This IQ/OQ Protocol specifically applies to the Applied Biosystems 9800 FAST Thermal Cycler as configured and installed according to Applied Biosystems' specifications. This IQ/OQ Protocol does not apply to any other products, processes, or optional components, unless specifically stated in this document, and is not to be used in conjunction with any other products or processes.

4.3 This IQ/OQ Protocol does not address any owner-specific analytical protocol (Performance Qualification) or method validation. Development and execution of a performance qualification protocol for the Applied Biosystems 9800 FAST Thermal Cycler is the responsibility of the instrument owner.

4.4 Applied Biosystems makes no representation whatsoever that this IQ/OQ Protocol satisfies or will satisfy any requirements of any governmental body or other organization, including, but not limited to, any requirement of the United States Food and Drug Administration (FDA) or the International Organization for Standardization (ISO). The instrument owner agrees that the instrument owner is responsible to verify that this IQ/OQ Protocol or this IQ/OQ service is adequate to meet its regulatory and certification requirements and that all requirements of any governmental body or other organization, including but not limited to any requirement of the U.S. Food and Drug Administration or the International Organization for Standardization, are the responsibility of the instrument owner.

5 Responsibilities

5.1 Applied Biosystems developed this IQ/OQ Protocol for the Applied Biosystems 9800 FAST Thermal Cycler and is responsible for revision control of the IQ/OQ Protocol.

5.2 The owners' organization executing the IQ/OQ Protocol is responsible for completing the "Conducted By" section associated with each task to indicate the verification was completed, results were within any specifications identified and exceptions have been documented.

5.3 The instrument owner is responsible for reviewing the entries made and for accepting these entries by signing under "Customer Signature." This signifies customer agreement with the entries made. In the case of exceptions recorded on the page, the owner is responsible for resolving exceptions arising from instrument installation or operation that do not meet Applied Biosystems specifications.

5.4 IQ/OQ Protocol and Report Approval Signatures are to be completed according to the procedures of the instrument owner's organization. Report approvals should be by individuals in the same function or organization that originally approved the IQ/OQ Protocol.

5.5 Should a new instrument in the process of installation not meet the operational specifications or other requirements in this IQ/OQ Protocol, Applied Biosystems will be responsible for effecting repair or replacement of the instrument to ensure operational specifications are met, subject to the terms of the Applied Biosystems warranty. If the execution of the IQ/OQ Protocol activities are interrupted by an instrument or power failure due to main power loss or disruption, the owner will of the instruments will be responsible for purchasing a new IQ/OQ Protocol to certify the instrument. Any damage to the instrument caused by such a power disruption will be repaired at the owner's expense. No refunds will be granted.

5.6 If a previously installed instrument does not meet the operational specifications or other requirements in this protocol, the instrument owner is responsible for repairing the instrument, or having it repaired, at the owner's expense, except to the extent that the instrument and the required repairs are covered by an Applied Biosystems warranty or service contract. If the execution of the IQ/OQ Protocol activities are interrupted by failure to meet such specification or other requirement, the owner of the instruments will be responsible for purchasing a new IQ/OQ Protocol to certify the instrument and the owner will be responsible for purchasing a new IQ/OQ Protocol to certify the instrument. No refunds will be granted.

6 Reporting Data

6.1 The completed IQ/OQ will consist of this approved IQ/OQ Protocol, completed in clear handwriting in blue or black ink with appended documents as listed in data sheet sections.

6.2 When each test page or check page is completed, it shall be signed and dated by the personnel carrying out the tests or checks.

6.3 The protocol requires a reviewer's signature from a suitable person on each test or page and at the end of the report indicating the satisfactory review and check of the report results.

6.4 The personnel completing the protocol should enter any comments regarding their findings in the relevant comments section for the Final Approver's attention. These may be continued in an appendix as necessary. Individual comments must be initialed and dated. The reviewers and approvers of the completed report may add their own initialed and dated responses to the comments if necessary.

6.5 All printouts and other supporting data, including CDs must be cross referenced to the specific test in this protocol, signed and dated, then inserted into the envelope at the back of the IQ/OQ binder.

7 System Description

The Applied Biosystems 9800 FAST Thermal Cycler is an automated instrument designed for the amplification of nucleic acids using the Polymerase Chain Reaction (PCR) process. The Applied Biosystems 9800 FAST Thermal Cycler has two components:

- Base module
- Sample block module.

The base module has a user interface that consists of a control panel with a full numeric keypad with soft keys and a graphical display screen showing time and temperature profiles for each run, as well as pre-PCR holds, PCR cycling, and post-PCR holds.

The sample block modules are interchangeable to allow changes in sample well formats and throughput capacity.

8 Recommendation for Performing the Instrument Performance Verification (IPV) Protocol

Applied Biosystems recommends that the Applied Biosystems 9800 FAST Thermal Cycler Instrument Performance Verification (IPV) diagnostics be performed to verify performance of the instrument after any of the following events:

- Replacement of any part that is critical to the performance of the Applied Biosystems 9800 FAST Thermal Cycler.
- Performance of any service procedure that may affect instrument performance.

The following table lists the applicable parts and procedures.

Part/Service/Maintenance Procedure
Applied Biosystems 9800 FAST Thermal Cycler Tests and Diagnostics • Applied Biosystems 9800 Fast Thermal Cycler With 96 Well Aluminum Sample Block Module Users Guide: Part Number—4350087 Chapter 2
o The Calibration Verification Test Pages 2-2 to 2-8
o System Performance Diagnostics Pages 2-16 to 2-18
Note: Pass/Fail Criteria are outlined in the users manual at the end of each section

9 Installation Qualification (IQ) Procedure

9.1 Procedure for IQ

9.1.1 The procedure can be performed by visual confirmation, supporting documentation, or by testing as described in the appropriate sections. The method of confirmation is to be indicated in the "Method" column of each Verification Data Sheet attached to this document.

9.1.2 Any discrepancies between the specified equipment parameters and those found on site are to be identified under exceptions and explained in the "Comments/Observations" section on the appropriate Verification Data Sheet.

9.1.3 Installation Qualification includes the following procedures in the sections indicated below.

Section and Procedure	Description
9.2 Order Verification	This procedure verifies that the Applied Biosystems 9800 FAST Thermal Cycler was received as ordered in name and part number. Perform and document the verifications required in the Order Verification data sheet. If available, attach a copy of the Purchase Order, Purchase Requisition, or other ordering documentation to this IQ/OQ documentation package.
9.3 Documentation Verification	This procedure verifies the existence of documentation available for use prior to the execution of the IQ/OQ. Perform the document verifications required by the Documentation Verification data sheet.
9.4 System Description and Identification Verification	This procedure verifies the identity of the system and subsystems of the Applied Biosystems 9800 FAST Thermal Cycler. Perform and document verifications required by the System Description and Identification Verification data sheet.
9.5 Utility Description Verification	This procedure verifies the existence of the utilities required to operate the Applied Biosystems 9800 FAST Thermal Cycler. Perform and document the verifications required by the Utility Description Verification data sheet.
9.6 Customer-Supplied Materials Verification	This procedure verifies the existence of the list of Applied Biosystems recommended customer-supplied materials. Perform and document the verifications required by the Customer-Supplied Materials Verification data sheet.
9.7 Emissions and Immunity Compliance Verification	This procedure verifies that the Emissions and Immunity status documentation are present and acceptable. Perform and document the verifications required by the Emissions and Immunity Compliance Verification data sheet.
9.8 Laboratory Environmental Operating Conditions Verification	This procedure verifies the identification of environmental conditions for the Applied Biosystems 9800 FAST Thermal Cycler. Perform and document the verifications required by the Laboratory Environmental Operating Conditions Verification data sheet.
9.9 Calibration and Maintenance Verification	This procedure verifies that the Applied Biosystems 9800 FAST Thermal Cycler is covered by an Applied Biosystems Warranty or Service Contract, or the user has a documented maintenance schedule and a record of maintenance.
9.10 Installation Verification	This procedure verifies that the Applied Biosystems 9800 FAST Thermal Cycler installation was completed as specified. Perform and document verifications required by the Installation Verification data sheet.

9.11 Software Identification Verification	This procedure verifies the establishment of software documentation and records for the Applied Biosystems 9800 FAST Thermal Cycler. Perform and document the verifications required by the Software Identification Verification data sheet.
9.12 IQ Completion Verification	This section verifies that the IQ has been executed, the IQ Report has been written, and the IQ acceptance criteria have been met or explained. Perform and document the verifications required by the IQ Completion Verification data sheet.

9.2 Order Verification

Perform and document the verification activities listed below.

	Activity	Method		
		V	D	T
9.2.1.	Verify that the product received matches the product ordered. Use the Purchase Order or other documentation to verify. Insert supporting documentation in the envelope at the back of the IQ/OQ binder.			

Exceptions:

Comments:

Acceptance Criteria: There is documented evidence that the instrument on site is what was ordered, except as noted above.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "Conducted By Signature" line above.

9.3 Documentation Verification

Complete the table below. Verify that the following user and service documents are available, and the title for each document is correct. On the "Part Number" and "Revision" lines, enter the document part number and revision letter.

	Activity	Method		
		V	D	T
9.3.1.	*Applied Biosystems FAST Thermal Cycler 9800 Base Module User's Manual* Part number: 4350088 Revision: _____ Location on site: _____			
9.3.2.	*Applied Biosystems 9800 Fast Thermal Cycler With 96-Well Aluminum Sample Block Module User Guide* Part number: 4350087 Revision: _____ Location on site: _____			

Exceptions:

Comments:

Acceptance Criteria: User and/or Service documents are on-site or available, except as noted above.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "Conducted By Signature" line above.

9.4 System Description and Identification Verification

Perform and document the verification activities listed below.

	Activity	Method V	Method D	Method T
9.4.1.	Verify that the general description of the Applied Biosystems 9800 Fast Thermal Cycler as specified in Section 7 of this IQ/OQ Protocol, matches the installed system.			
9.4.2	Complete the following:			
a.	**Applied Biosystems 9800 Fast Thermal Cycler Base Module** Equipment Model: _____ Serial Number: _____ Lab Location: _____ **Applied Biosystems 9800 Fast Thermal Cycler Sample Block Module** Equipment Model: _____ Serial Number: _____ Lab Location: _____			
b.	**Optional Printer** Manufacturer: _____ Equipment Number: _____ Serial Number: _____ Lab Location: _____			

Exceptions:

Comments:

Acceptance Criteria: All the above information has been verified and is acceptable, except as noted above.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "Conducted By Signature" line above.

9.5 Utility Description Verification

Perform and document the verification activities listed below.

	Activity	Method		
		V	D	T
9.5.1.	Verify that the laboratory meets the Laboratory Space and Layout Requirements, as specified in the *Applied Biosystems 9800 Fast Thermal Cycler With 96 Well Aluminum Sample Block Module Users Guide.* Page number: _____			
9.5.2.	Verify that the that the laboratory meets the *Chemical Safety Guidelines*, as specified in the *Applied Biosystems 9800 Fast Thermal Cycler With 96 Well Aluminum Sample Block Module Users Guid*e. Page number: _____ Insert supporting documentation in the envelope at the back of this IQ/OQ Protocol binder.			
9.5.3.	Verify that the laboratory meets the *Ventilation Requirement*s, as specified in the *Applied Biosystems 9800 Fast Thermal Cycler With 96 Well Aluminum Sample Block Module Users Guide.* Page number: _____ Insert supporting documentation in the envelope at the back of this IQ/OQ Protocol binder.			
9.5.4.	Verify that the laboratory meets the *Electrical Requirements*, as specified in the *Applied Biosystems 9800 Fast Thermal Cycler With 96 Well Aluminum Sample Block Module Users Guide.* Page number: _____ Insert supporting documentation in the envelope at the back of this IQ/OQ Protocol binder.			

Exceptions:

Comments:

Acceptance Criteria: All the above information has been verified and documented, and is acceptable, except as noted above.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "Conducted By Signature" line above.

9.6 Safety Materials Verification

Confirm and document the verification requirements listed below.

	Requirement	Method		
		V	D	T
9.6.1.	Verify that the user supplied safety equipment, as specified in the *Applied Biosystems 9800 Fast Thermal Cycler With 96 Well Aluminum Sample Block Module Users Guide, Chemical safety guidelines section*, are available. Page number: _____			

Exceptions:

Comments:

Acceptance Criteria: The above requirements have been met, in accordance with the site safety regulations.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "Conducted By Signature" line above.

9.7 Emissions and Immunity Compliance Verification

Perform and document the verification activities listed below.

	Activity	Method		
		V	D	T
9.7.1.	The customer signature below verifies that the owner/user has read the *Safety and Electromagnetic Compatibility (EMC) standards* section of the *Applied Biosystems 9800 Fast Thermal Cycler With 96 Well Aluminum Sample Block Module Users Guide.* Page number: _____			

Exceptions:

Comments:

Acceptance Criteria: All of the above requirements have been met.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "Conducted By Signature" line above.

9.8 Laboratory Environmental Operating Conditions Verification

Confirm and document the verification requirements listed below.

	Requirement	Method*		
		V	D	T
9.8.1.	Verify that the laboratory meets the Altitude Requirements, as specified in the *Temperature, Humidity and Environment* section of the *Applied Biosystems 9800 Fast Thermal Cycler With 96 Well Aluminum Sample Block Module Users Guide*. Insert supporting documentation in the envelope at the back of the IQ/OQ binder. Page number: _____			
9.8.2.	Verify that the laboratory meets the Pollution Requirements, as specified in the *Temperature, Humidity and Environment* section of the *Applied Biosystems 9800 Fast Thermal Cycler With 96 Well Aluminum Sample Block Module Users Guide*. Insert supporting documentation in the envelope at the back of the IQ/OQ binder. Page number: _____			
9.8.3.	Verify that the laboratory meets the Temperature and Humidity Requirements, as specified in the *Temperature, Humidity and Environment* section of the *Applied Biosystems 9800 Fast Thermal Cycler With 96 Well Aluminum Sample Block Module Users Guide*. Insert supporting documentation in the envelope at the back of the IQ/OQ binder. Page number: _____			

Exceptions:

Comments:

Acceptance Criteria: Documentation reflects requirements in Chapter 1 of the Site Preparation Guide.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "EXECUTED By: Signature" section above.

The AB (Design) and this sentence must be BLUE in color.

9.9 Calibration and Maintenance Verification

Perform and document the verification activities listed below.

	Activity	Method*		
		V	D	T
9.9.1	Verify that the 9800 Fast Thermal Cycler is covered by an Applied Biosystems warranty or service contract. If applicable, insert a copy of the most recently completed Applied Biosystems 9800 Fast Thermal Cycler "Certificate of Analysis" in the envelope at the back of this IQ/OQ Protocol binder. Note: Some service contract types do not include scheduled maintenance. Note: Review the Applied Biosystems warranty of the 9800 Fast Thermal Cycler for warranty details, including warranty period and coverage. Planned Maintenance ("PM") is not included in warranty coverage. Warranty/Contract expiration date: _____ If the 9800 Fast Thermal Cycler is **not** covered by an Applied Biosystems warranty or service contract, verify that the customer has a documented maintenance schedule and record of maintenance performed for the 9800 Fast Thermal Cycler. Insert supporting documentation in the envelope at the back of this IQ/OQ Protocol binder.			
9.9.2	It is recommended that the Applied Biosystems 9800 Fast Thermal cycler have an annual calibration performed by an Applied Biosystems Repair center or Applied Biosystems authorized service provider using a multi-channel calibration system tool. The instrument that is having the IQ/OQ performed must have a calibration performed prior to the execution of the IQ/OQ Protocol. Insert the most recent Certificate of Analysis in the envelope at the back of the IQ/OQ binder.			

Note: Applied Biosystems does not endorse the suitability of any proposed maintenance plan or schedule that is not provided by Applied Biosystems for this instrument. Any customer electing not to have an instrument covered by an Applied Biosystems Service Contract or Maintenance agreement must clearly document all maintenance activities performed on the instrument for future reference.

Exceptions:

Comments:

Acceptance Criteria: All the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "Executed By Signature" section above.

The AB (Design) and this sentence must be BLUE in color.

9.10 Installation Verification

Perform and document the verification activities listed below.

Activity		Method*		
		V	D	T
9.10.1.	Verify that the system components are unpacked according to the instructions in the *Applied Biosystems 9800 Fast Thermal Cycler Base Module User Guide.*			

Exceptions:

Comments:

Acceptance Criteria: All the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

* V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "EXECUTED By: Signature" section above.

The AB (Design) and this sentence must be BLUE in color.

9.11 Software Identification Verification

Perform and document the verification activities listed below.

	Activity	Method*		
		V	D	T
9.11.1.	Verify that the version o firmware installed on the Applied Biosystems 9800 FAST Thermal Cycler. Instrument Firmware Minimum Version required _1.0_ Version installed _____			

Exceptions:

Comments:

Acceptance Criteria: The following signatures indicate that the software verifications above have been documented and any exceptions noted.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

* V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "EXECUTED By: Signature" section above.

The AB (Design) and this sentence must be BLUE in color.

9.12 IQ Completion Verification

Perform and document the verification activities listed below.

	Activity	Method*		
		V	D	T
1.	Verify that the IQ has been completely executed.			
2.	Verify that all exceptions have been investigated and documented.			

Exceptions:

Comments:

Acceptance Criteria: All the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

* V = Visually verified
D = Documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "EXECUTED By": Signature" section above.

10 Operation Qualification (OQ) Procedure

10.1 Procedure for OQ Execution

10.1.1 The procedure can be performed by visual confirmation, supporting documentation, or by testing as described in the appropriate sections. The method of confirmation is to be indicated in the "Method" column of each Verification Data Sheet attached to this document.

10.1.2 Any discrepancies between the specified equipment parameters and those found on site are to be documented and explained in the "Comments/Observations" section of the appropriate Verification Data Sheet.

10.1.3 Operation Qualification includes the following procedures in the sections indicated below.

Section and Procedure	Description
10.2 Loss of Power	This test verifies that the Applied Biosystems 9800 FAST Thermal Cycler is able to properly begin a new run after power is restored and that the Power Failure Test has been completed and documented.
10.3 Operation Qualification	This test is performed to check, document, and verify that the Applied Biosystems 9800 FAST Thermal Cycler meets the operational specifications for the Main Menu Screen and Function Verification for the Applied Biosystems 9800 FAST Thermal Cycler. Perform and document the verifications required by the Operation Qualification Verification data sheet. Include data generated with this protocol.
10.4 Training of Users Verification	This procedure verifies that the instrument owner(s) received training on operation of the Applied Biosystems 9800 FAST Thermal Cycler. Perform and document the verifications required by the Training of Users Verification data sheet.

10.2 Loss of Power Verification

The Applied Biosystems 9800 FAST Thermal Cycler has been designed to continue a run after a power failure occurs. However, due to the inconsistent nature of unplanned power outages, we recommend that the samples be re-run. The following verification is designed to ensure that if a power failure does occur, the instrument is able to resume the run in progress properly after power is restored.

	Activity	Method*		
		V	D	T
1.	While the Applied Biosystems 9800 FAST Thermal Cycler is in normal operation, simulate the Loss of Power Test to the equipment/system. Perform Loss of Power by unlatching the Top Module latch, part number N8051024. The Loss of Power Test requires a minimum of five (5) minutes. After the power failure test, restore power to the instrument/system.			
2.	Please circle yes or no to the following: a. Verifications/Test Results: Was the system operating normally prior to the simulated Power Losses? (yes / no) b. When electrical power to the equipment/system is removed, the Applied Biosystems 9800 FAST Thermal Cycler is non-operational. (yes / no) c. Was the time period for the simulated power failure and restart greater than five (5) minutes? (yes / no) d. When electrical power is restored to the system, the Applied Biosystems 9800 FAST Thermal Cycler returns to its normal operating condition. (yes/no) The answer to ALL should be yes.			

Exceptions:

Comments:

Acceptance Criteria: There is documented evidence of training.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

* V = Visually verified
D = Certification/documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "Conducted by" section above.

10.3 Operation Qualification

From the user's interface, enter each of the screens specified in the table below. Confirm by checking Yes or No, that each of the screens listed in the table below is accessible from the user's interface and functions as specified.

Note: A response of 'X' in the Expected Output can stand for any alphanumeric symbol.

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the power switch to the ON position (*system start up cycling*).	Power light on front panel is lit (red).	**Yes** ☐ **No** ☐	
System starts up cycling	A whirling fan sounds. Display output: *APPLIED BIOSYSTEMS* *www.appliedbiosystems.com*	**Yes** ☐ **No** ☐	
System starts up cycling.	Display output: *Applied Biosystems* *Applied Biosystems 9800 System* *Fast Thermal Cycler* *Version X.XX*	**Yes** ☐ **No** ☐	
System start up cycle. (Complete)	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *Name: XXXX User: xxxx* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *Util* soft key.	Display output: *Utilities* *Diag – Instrument diagnostics* *TmCalc – Calculates melting temp* *Config – Instrument configuration* *Diag TmCalc Config More Exit*	**Yes** ☐ **No** ☐	

10.3 Operation Qualification (continued)

Press the *Config* soft key. THEN **IF** the daytime is in the **AM**, press the *PM* soft key; if not, do not press the *PM* soft key.	Display output: *Instrument Configuration* *Time:* *XX: XX PM* *Date:* *XX/XX/00 M/D/Y* *Run Time Printer: Off* *Run Time Beep: Off* *Accept* *AM* *24 Hr* *More* *Cancel*	**Yes** ☐ **No** ☐	
Press the *circular key* in up/down/side(s) mode to verify the LCD screen can 'highlight' the following: time display, date display (month/date/year), Off (run time printer), & Off (run time beep).	Pressing the *circular key* in up/down/side(s) mode 'highlights' the following: time display, date display (month/date/year), Off (run time printer), & Off (run time beep).	**Yes** ☐ **No** ☐	
Press the *circular key* to 'highlight' month in the date display.	Display output: *Instrument Configuration* *Time:* *XX: XX PM* *Date:* *XX/XX/XX M/D/Y* *Run Time Printer: Off* *Run Time Beep: Off* *Accept* *D/M/Y* *Y/M/D* *More* *Cancel*	**Yes** ☐ **No** ☐	

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the D/M/Y soft key.	Display output: *Instrument Configuration* *Time: XX: XX PM* *Date: XX/XX/XX D/M/Y* *Run Time Printer: Off* *Run Time Beep: Off* *Accept Y/M/D M/D/Y More Cancel*	**Yes ☐ No ☐**	
Press the Y/M/D soft key.	Display output: *Instrument Configuration* *Time: XX: XX PM* *Date: XX/XX/XX Y/M/D* *Run Time Printer: Off* *Run Time Beep: Off* *Accept M/D/Y D/M/Y More Cancel*	**Yes ☐ No ☐**	
Press the M/D/Y soft key.	Display output: *Instrument Configuration* *Time: XX: XX PM* *Date: XX/XX/XX M/D/Y* *Run Time Printer: Off* *Run Time Beep: Off* *Accept D/M/Y Y/M/D More Cancel*	**Yes ☐ No ☐**	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *circular key* to 'highlight' the following: Off (run time printer).	Display output: *Instrument Configuration* *Time:* *XX: XX PM* *Date:* *XX/XX/XX M/D/Y* *Run Time Printer: Off* *Run Time Beep: Off* *Accept* *On* *Off* *More* *Cancel*	**Yes** ☐ **No** ☐	
Press the *On* soft key and then the *Off* soft key.	Display output: Run Time Printer 'highlight' on the LCD screen toggles *On* then *Off*.	**Yes** ☐ **No** ☐	
Press the *circular key* to 'highlight' the following: Off (run time beep).	Display output: *Instrument Configuration* *Time:* *XX: XX PM* *Date:* *XX/XX/XX M/D/Y* *Run Time Printer: Off* *Run Time Beep: Off* *Accept* *On* *Off* *More* *Cancel*	**Yes** ☐ **No** ☐	
Press the *On* soft key and then the *Off* soft key.	Display output: Run Time Beep 'highlight' on the LCD screen toggles *On* then *Off*.	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *circular key* to 'highlight' the following: XX: XX (Time).	Display output XX: XX highlighted on time: *Instrument Configuration* *Time: XX: XX PM* *Date: XX/XX/XX M/D/Y* *Run Time Printer: Off* *Run Time Beep: Off* *Accept AM 24 Hr. More Cancel*	**Yes ☐ No ☐**	
Press the *24 Hr* soft keys.	Display output: *Instrument Configuration* *Time: XX: XX 24 Hour* *Date: XX/XX/XX M/D/Y* *Run Time Printer: Off* *Run Time Beep: Off* *Accept PM AM More Cancel*	**Yes ☐ No ☐**	
Press the A*M* soft key.	Display output: *Instrument Configuration* *Time: XX: XX AM* *Date: XX/XX/XX M/D/Y* *Run Time Printer: Off* *Run Time Beep: Off* *Accept 24 Hr PM More Cancel*	**Yes ☐ No ☐**	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *PM* soft key.	Display output: *Instrument Configuration* *Time: XX: XX PM* *Date: XX/XX/XX M/D/Y* *Run Time Printer: Off* *Run Time Beep: Off* *Accept AM 24Hr More Cancel*	**Yes ☐ No ☐**	
If the current time is in the AM press the *AM* soft key. If the current time is in the PM, press the *Accept* key.	Display output: *Utilities* *Diag – Instrument diagnostics* *TmCalc – Calculates melting temp* *Config – Instrument configuration* *Diag TmCalc Config More Exit*	**Yes ☐ No ☐**	
Press the *Config then More* soft keys.	Display output: *Instrument Configuration* *Pause Time Out: 10:00 (00:01-99:59)* *Idle State Set point: 25.0 C (4.0-99.9)* *Baud Rate: 9600* *Accept More Cancel*	**Yes ☐ No ☐**	
Press the *circular key* to 'highlight' the following: XX.X (Idle State Set Point).	Display output: *Instrument Configuration* *Pause Time Out: 10:00 (00:01-99:59)* *Idle State Set point: 25.0 C (4.0-99.9)* *Baud Rate: 9600* *Accept More Cancel*	**Yes ☐ No ☐**	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *circular key* to 'highlight' the following: XXXX (Baud Rate).	Display output: *Instrument Configuration* *Pause Time Out: 10:00 (00:01-99:59)* *Idle State Set point: 25.0 C (4.0-99.9)* *Baud Rate: 9600* *Accept Up Down More Cancel*	**Yes ☐ No ☐**	
Press the *Up* soft key 'once' and the *Down* soft key 'once'. Press the *Accept* soft key.	Display output for the Baud Rate reads 19200 when the *Up* soft key is pressed and 9600 when the *Down* soft key is pressed.	**Yes ☐ No ☐**	
Press the *Config, More*, & *More* soft keys in succession.	Display output: *Instrument Configuration* *Screen Contrast: 7 (1 to 20)* *Screen Saver: Smart* *Accept Up Down More Cancel*	**Yes ☐ No ☐**	
Press the *Up* soft keys once then the *Down* soft key once.	Display output for Screen Contrast increases to 8 then decreases to 7 as the soft keys are pressed.	**Yes ☐ No ☐**	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature: _____ Date: _____

Customer Signature: _____ Date: _____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *circular key* to 'highlight' the following: Screen Saver Smart	Display output: *Instrument Configuration* *Screen Contrast: 7 (1-20)* *Screen Saver: Smart* *Accept Always Never More Cancel*	**Yes ☐ No ☐**	
Press the *Accept* soft key.	Display output: *Utilities* *Diag – Instrument diagnostics* *TmCalc – Calculates melting temp* *Config – Instrument configuration* *Diag TmCalc Config More Exit*	**Yes ☐ No ☐**	
Press *Config, More, More, More*, soft keys in succession.	Display output: *Instrument Configuration* *Get IP: Off Name: XXXXXXXX* *Accept + - More Cancel*	**Yes ☐ No ☐**	
Verify NAME in display is the unit serial #.	Display output: *Instrument Configuration* *Get IP: Off Name: XXXX* *Accept + - More Cancel*	**Yes ☐ No ☐** Unit S/N _____	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

The AB (Design) and this sentence must be BLUE in color.

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Cancel* soft key.	Display output: *Utilities* *Diag – Instrument diagnostics* *TmCalc – Calculates melting temp* *Config – Instrument configuration* *Diag TmCalc Config More Exit*	**Yes** ☐ **No** ☐	
Press the *Diag* soft key.	Display output: *Diagnostics* *Hard – Hardware Diagnostics* *System – System Performance Tests* *TmpVer – Temperature Verification* *Upgrad – Firmware Upgrade* *Hard System TmpVer Upgrad Exit*	**Yes** ☐ **No** ☐	
Hardware Testing Press the *Hard* soft key.	Display output: *Hardware Diagnostics* *Disp – LCD Display Diagnostic* *Keypad – Keypad Diagnostic* *Disp Keypad Exit*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Disp* soft key.	Display output: *Display Diagnostics* *1. Read all instructions first.* *2. Press Run to turn ON all pixels.* *3. Press STOP to turn OFF all pixels.* 4. *Press STOP to exit.* *Run* *Exit*	**Yes** ☐ **No** ☐	
Press the *Run* soft key.	Display output: All pixels ON.	**Yes** ☐ **No** ☐	
Press the *Stop* soft key.	Display output: All pixels OFF.	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Stop* soft key.	Display output: *Hardware Diagnostics* *Disp – LCD Display Diagnostic* *Keypad – Keypad Diagnostic* *Disp Keypad Exit*	**Yes** ☐ **No** ☐	
Press the *Keypad* soft key.	Display output: Keypad Diagnostic After pressing Run, press the blinking key or press STOP twice to exit. Run Exit	**Yes** ☐ **No** ☐	
Press the *Run* soft key.	Display output (F1 blinking): *F1 F2 F3 F4 F5* *STOP 1 2 3 ^* *4 5 6 < >* *7 8 9 v* *ENTER 0 CE*	**Yes** ☐ **No** ☐	
Press the indicated *blinking* keypad button one time until all blinking keys are 'lit' on the display.	Display output: *F1 F2 F3 F4 F5* *STOP 1 2 3 ^* *4 5 6 < >* *7 8 9 v* *ENTER 0 CE*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

The AB (Design) and this sentence must be BLUE in color.

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the 'last' *blinking* key to be 'lit' from test.	Display output: *Hardware Diagnostics* *Disp – LCD Display Diagnostic* *Keypad – Keypad Diagnostic* *Disp Keypad Exit*	**Yes ☐ No ☐**	
Press the *Exit soft* key.	Display output: *Diagnostics* *Hard – Hardware Diagnostics* *System Hard – System Performance Tests* *TmpVer – Temperature Verification* *Upgrad – Firmware Upgrade* *Hard System TmpVer Upgrad Exit*	**Yes ☐ No ☐**	
System Test Press the *System soft k*ey.	Display output: *System Performance* *Rate – Cool and Heat Rate Test* *Cycle – Cycle Performance Test* *Rate Cycle Exit*	**Yes ☐ No ☐**	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Rate* soft key.	Display output: *WARNING! ! !* *Install the appropriate empty Consumables into the Sample Block.* *Refer to System Performance Section of Block User Manual.* *Cont* *Cancel*	**Yes** ☐ **No** ☐	
If a Consumable tray is **not** already installed in the instrument, Place a Consumable tray into the unit and secure the lid. Press the *Cont* soft key.	Display output: *Cool and Heat Rate Test* *Blk XX.X C* *Ramping sample block to 35.0 C* *Cancel*	**Yes** ☐ **No** ☐	
Continue	Display output: *Cool and Heat Rate Test* *Blk XX.X C* *Stabilizing sample block at 35.0 C* *Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Continue	Display output: *Cool and Heat Rate Test Blk XX.X C* *Ramping Block to 95.0 C* *Cancel*	**Yes** ☐ **No** ☐	
Continue	Display output: *Cool and Heat Rate Test Blk XX.X C* *Stabilizing sample block at 95.0 C* *For 1 min . . .X: XX* *Cancel*	**Yes** ☐ **No** ☐	
Continue	Display output: *Cool and Heat Rate Test Blk XX.X C* *Ramping sample block to 4.0 C* *Cancel*	**Yes** ☐ **No** ☐	
Continue (Final screen)	Display output: *Cool and Heat Rate Test Pass* *Heating rate: X.XX C/s* *Cooling rate: X.XX C/s* *Print Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Cancel* soft key.	Display output: *System Performance* *Rate – Cool and Heat Rate Test* *Cycle – Cycle Performance Test* *Rate Cycle Exit*	**Yes** ☐ **No** ☐	
Press the *Cycle* soft key.	Display output: *WARNING! ! !* *Install the appropriate empty Consumables into the Sample Block.* *Refer to System Performance Section of Block User Manual.* *Cont Cancel*	**Yes** ☐ **No** ☐	
Press *Cont* soft key.	Display output (HOT may be blinking in display): Test thermal cycler program running *Pause Info*	**Yes** ☐ **No** ☐	
Press the *Info* soft key.	Display output: *XX: XX XM Information XX.XC* *User: <<ab>> Method: Cycle Test* *Run Started at XX: XX: XX XM, XX/XX/XX.* *Run will end at XX: XX: XX XM, XX/XX/XX.* *Reaction vol: X uL Ramp speed: HS96 (Alternate – STD)* *Return*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Return* soft key or wait 10 seconds for screen to return automatically.	Display output (HOT may be blinking in display): Test thermal cycler program running *Pause* *Info*	**Yes** ☐ **No** ☐	
Press the *Pause* soft key.	Display output (HOT may be blinking in display): Test thermal cycler program running *Resume Paused. Will resume in X: XX*	**Yes** ☐ **No** ☐	
Press the *Resume* soft key.	Display output (HOT may be blinking in display): Test thermal cycler program running *Pause* *Info*	**Yes** ☐ **No** ☐	
Let thermal cycler test program finish cycle.	Display output: *Cycle Performance* *Pass* *Average Cycle Time: XXX.X sec* *Cycle Time STD: X.X sec* *Print* *Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Cancel* soft key.	Display output: *System Performance* *Rate – Cool and Heat Rate Test* *Cycle – Cycle Performance Test* *Rate Cycle Exit*	**Yes** ☐ **No** ☐	
Press the *Exit* soft key.	Display output: *Diagnostics* *Hard – Hardware Diagnostics* *System – System Performance Tests* *TmpVer – Temperature Verification* *Upgrad – Firmware Upgrade* *Hard System TmpVer Upgrad Exit*	**Yes** ☐ **No** ☐	
If a Consumable tray is installed in the instrument, open the lid and remove it.	Display output: *Diagnostics* *Hard – Hardware Diagnostics* *System – System Performance Tests* *TmpVer – Temperature Verification* *Upgrad – Firmware Upgrade* *Hard System TmpVer Upgrad Exit*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Temperature Verification		**Yes ☐ No ☐**	
Press the *TmpVer soft* key.	Display output: *Temperature Verification* *Temp – Calibration Verification* *TNU – Temperature Non-Uniformity* *Temp TNU Exit*		
Press the *Temp* soft key. *Place probe in well A6.* *Close the Heated cover (Lid)* *Press Run.*	Display output: *Calibration Verification* *Block temp = XX.X ^{0}C Cover temp = XXX ^{0}C* *Place Probe in Well A6* *Press run* *Run Cancel*	**Yes ☐ No ☐**	
	Display Output: *Calibration Verification* *Block temp = XX.X ^{0}C Cover temp = XXX ^{0}C* *Set point is 85C* *Cover must be within 10^{0}C of 85^{0}C* *Cancel*	**Yes ☐ No ☐**	
	Display Output: *Calibration Verification* *Block temp = XX.X °C Cover temp = XX °C* *Stabilizing at set point…… X:XX (3 min Timer)*	**Yes ☐ No ☐**	
Press *Enter* after entering actual block temperature.	Display output for 96-well and 60-well systems: *Calibration Verification* *Block temp = XX.X ^{0}C Cover temp = XXX ^{0}C* *Enter actual block temperature* 00.0 *Cancel*	**Yes ☐ No ☐**	

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
	Display output: *Calibration Verification* *Block temp = XX.X ^{0}C Cover temp = XXX ^{0}C* *Set point is 45 C* *Cover must be within 30^{0}C of 45^{0}C* *Cancel*	**Yes ☐ No ☐**	
	Display Output: *Calibration Verification* *Block temp = XX.X ^{0}C Cover temp = XX ^{0}C* *Stabilizing at set point ……. X:XX ^{0}C (3 min Timer)* *Cancel*	**Yes ☐ No ☐**	
Press *Enter* after entering block temperature on the keypad.	Display output: *Calibration Verification* *Block temp = 45.0 ^{0}C* *Cover temp = XX. ^{0}C* *Enter actual block temperature:* 00.0 *Cancel.*	**Yes ☐ No ☐**	
Press *Accept.*	Display output: *Calibration Verification* *Actual temperature at 85 ^{0}C: XX.X* *Actual temperature at 45 ^{0}C: XX.X* *Accept* *Cancel*	**Yes ☐ No ☐**	
If calibration is good, press *Exit.* *Open the Heated cover (Lid).* *Remove the probe.*	Display output: Calibration Verification Calibration is good *Exit*	**Yes ☐ No ☐**	

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
If the test fails, repeat the procedure to make sure the digital thermometer was not misread or that data entry errors where not made. *If the test fails again, contact Applied Biosystems Technical Support.*	Alternate Display output: *Calibration Verification* Instrument may require service. Contact Applied Biosystems Technical Support *Exit*	**Yes** ☐ **No** ☐	
Press the *Exit* soft key.	Display output: *Temperature Verification* *Temp – Calibration Verification* *TNU – Temperature Non-Uniformity* *Temp TNU Exit*	**Yes** ☐ **No** ☐	
Press the *Exit soft* key.	Display output: *Diagnostics* *Hard – Hardware Diagnostics* *System – System Performance Tests* *TmpVer – Temperature Verification* *Upgrad – Firmware Upgrade* *Hard System TmpVer Upgrad Exit*	**Yes** ☐ **No** ☐	
Press the *Exit soft* key.	Display output: *Utilities* *Diag – Instrument diagnostics* *TmCalc – Calculates melting temp* *Config – Instrument configuration* *Diag TmCalc Config More Exit*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Exit* soft key.	Display output: *Time* *Date* *Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *Name XXXX* *User: xx* *Run* *Create* *Edit* *Util* *User*	**Yes** ☐ **No** ☐	
Press the *User* soft key; highlight <<ab>> with the Circular keypad.	Display output: *Select User Name* <<ab>> *XXX* *Accept* *New* *Edit* *Delete* *Cancel*	**Yes** ☐ **No** ☐	
Press the *New* soft key.	Display output: *abcdefghi* *jklmnopqr* *User Name* *stuvwxyz* *.,-+/():=* *Use ENTER key to select a character.* *Accept* *Backsp* *Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Enter, Circular Dial, & Keypad* to enter the name **'test1'**.	Display output: *abcdefghi* *jklmnopqr* *User Name test1* *stuvwxyz* *.,-+/():=* *Use ENTER key to select a character.* *Accept* *Backsp* *Cancel*	**Yes** ☐ **No** ☐	
Press the *Backsp* soft key.	Display output: *abcdefghi* *jklmnopqr* *User Name test* *stuvwxyz* *.,-+/():=* *Use ENTER key to select a character.* *Accept* *Backsp* *Cancel*	**Yes** ☐ **No** ☐	
Press the *Keypad* to enter the number '1'.	Display output: *abcdefghi* *jklmnopqr* *User Name test1* *stuvwxyz* *.,-+/():=* *Use ENTER key to select a character.* *Accept* *Backsp* *Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Accept* soft key.	Display output: *User name: test1* *PIN number: None* *Protection: Unlocked* *Press PIN # to create a #. Then you set protection to Locked to prevent methods from being over-written or deleted.* *Accept* *Name* *PIN #* *Cancel*	**Yes** ☐ **No** ☐	
Press the PIN # *soft key.*	Display output: *Create a PIN number* *Your PIN number protects the access to your user name and protection level* *Enter a PIN Number.* *New Pin #:* *Accept* *Cancel*	**Yes** ☐ **No** ☐	
Press the keypad #'s 123 and the *Accept* soft key.	Display output: *Confirm PIN Number* *Your PIN number protects the access to your user name and protection level* *Enter PIN number again.* *PIN #:* *Press Accept to confirm you PIN #.* *Accept* *Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Enter 321 from keypad and press the *Accept* soft key.	1. Display output (5 seconds): *User name: test1* *PIN number: XXX* *Protection: Unlocked* *Press PIN # to create a #. Then you set protection to Locked to prevent methods from being over-written or deleted.* *Invalid Password/pin #* 2. Display output: *Confirm PIN Number* *Your PIN number protects the access to your user name and protection level* *Enter PIN number again.* *PIN #:* *Press Accept to confirm you PIN #.* *Invalid Password pin#* *Accept* *Cancel*	**Yes** ☐ **No** ☐	
Enter 123 from keypad and press the *Accept* soft key.	Display output: *User name: test1* *PIN number: XXX* *Protection: Unlocked* *Press PIN # to create a #. Then you set protection to Locked to prevent methods from being over-written or deleted.* *Accept* *Name* *PIN#* *Lock* *Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Lock* soft key.	Display output: *User name: test1* *PIN number: XXX* *Protection: Locked* *Press PIN # to create a #. Then you set protection to Locked to prevent methods from being over-written or deleted.* *Accept Name PIN# Unlock Cancel*	**Yes** ☐ **No** ☐	
Press the *Unlock* soft key.	Display output: *User name: test1* *PIN number: XXX* *Protection: Unlocked* *Press PIN # to create a #. Then you set protection to Locked to prevent methods from being over-written or deleted.* *Accept Name PIN# Lock Cancel*	**Yes** ☐ **No** ☐	
Press the *Lock* soft key.	Display output: *User name: test1* *PIN number: XXX* *Protection: Locked* *Press PIN # to create a #. Then you set protection to Locked to prevent methods from being over-written or deleted.* *Accept Name PIN# Unlock Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

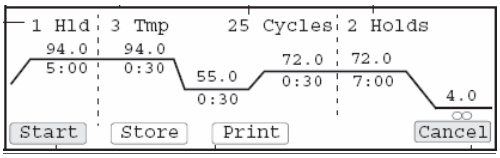
Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Accept* soft key.	Display output: *Select User Name* *<<ab>> XXX test1* *Accept New Edit Delete Cancel*	**Yes** ☐ **No** ☐	
Press the *Accept* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 FAST Thermal Cycler* *Version: X.XX* *User: test1* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *Create* soft key.	Display output: Default Method  F1 F2 F3 F5 Start Store Print Cancel	**Yes** ☐ **No** ☐	
Press the *Store* soft key.	Display output: *Store Method on Instrument* *User: test1* *Method: XX* *Ramp Mode: HS96 or STD* *Free Mem: XXX methods XXX segments* *Accept User Method Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Accept* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *Name: XXXX User: test1* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Using the previous methodology, create thermal cycler test2 (PIN #123 & unlocked) and test3 (No PIN #) and one stored program. Press the *User* soft key and highlight 'test1'. Press *Accept* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: test1* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *Run* & *Start* soft keys in succession.	Display output: Select Method Options Reaction volume: 30 uL Ramp speed: HS96 or Std Run ID 1 Enter a value from 5 to 30 uL Start Cancel	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Using the keypad enter 31 then press the *Start* soft key.	Display output: Select Method Options Reaction volume: 31 uL Ramp speed: HS96 or Std Run ID 1 Enter a value from 5 to 30 uL Valid range is 5 to 30	**Yes** ☐ **No** ☐	
Using the keypad enter 4 then press the *Start* soft key.	Display output: Select Method Options Reaction volume: 4 uL Ramp speed: HS96 or Std Run ID 1 Enter a value from 5 to 30 uL Valid range is 5 to 30	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
For 96-well and 60-well systems, using the keypad enter 25 then press the *Start* soft key. For 384-well systems, using the keypad enter 10 then press the *Start* soft key.	Display output: Please wait. Cover is heating. Current temperature: XXX°C The run will begin when the heated cover reaches 103°C. Cancel	**Yes** ☐ **No** ☐	

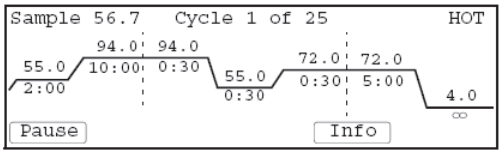
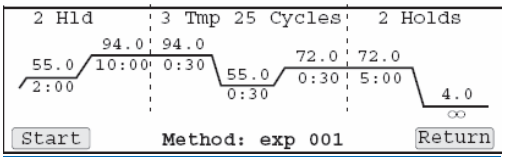
Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the STOP keypad button when the run begins.	Display output: Sample XX.X Confirm Stop HOT Confirm Stop Press STOP to abort. Press Resume to continue. Resume	**Yes** ☐ **No** ☐	
Press the *Resume* soft key.	Display output: Example Only HOT  *F1* *F2* *F3* *F4* *F5*	**Yes** ☐ **No** ☐	
Press the STOP keypad button two times in succession.	Display output (temperature may be blinking): *XX:XX XM* *End of Run* *XX.X°C* *Method: XXXXXXXX* *Run aborted at XX;XX:XX XM, XX/XX/XX.* *Length of run is XX:XX:XX.* *Hist* *Exit*	**Yes** ☐ **No** ☐	
Press the *Exit* soft key.	Display output: *Time* *Date* *Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: test1* *Run* *Create* *Edit* *Util* *User*	**Yes** ☐ **No** ☐	
Press the *Run* and *View* soft keys in succession.	Display output: Example Only  *Start* *Method: XX* *Return* *F1* *F2* *F3* *F4* *F5*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Return* and *Cancel* soft keys in succession.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *Name: XXXXX User: <<ab>>* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *Run* and *User* soft keys in succession.	Display output: Select User Name <<ab>> test1 test2 test3 XXXX Accept All Cancel	**Yes** ☐ **No** ☐	
Using the Circular Key, highlight the <<ab>> and press the *Accept* soft key.	Display output: All methods of <<ab>> displayed on screen *Start View User Sort Cancel*	**Yes** ☐ **No** ☐	
Press the *Cancel* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *Name: XXXXX User: <ab>>* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Run*, *User*, & *All* soft keys in succession.	Display output: All methods XXX displayed on screen *Start View User Sort Cancel*	**Yes ☐ No ☐**	
Press the *Cancel* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Name: XXXXX User: <<ab>>* *Run Create Edit Util User*	**Yes ☐ No ☐**	
Press the *Edit, User,* and *All* soft keys in succession.	Display output: *Methods User Size Last Used* *XXXX XXX XX XX/XX/XX* *XXXX XXX XX XX/XX/XX* *Edit View User Sort Cancel* Alternate Screen *Free Mem: XX methods XXX segments* *XXXX XXX XX XX/XX/XX* *XXXX XXX XX XX/XX/XX* *Edit View User Sort Cancel*	**Yes ☐ No ☐**	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

The AB (Design) and this sentence must be BLUE in color.

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Sort* soft key.	Display output: Sort Methods By: Method name Date last used Date stored Method size Accept Cancel	**Yes** ☐ **No** ☐	
With the Circular key, highlight 'Method name' and press *Accept* soft key.	Display output sorted alphabetically by Method name: *Methods User Size Last Used* *XXXX XXX XX XX/XX/XX* *XXXX XXX XX XX/XX/XX* *Edit View User Sort Cancel* Alternate Screen *Free Mem: XX methods XXX segments* *XXXX XXX XX XX/XX/XX* *XXXX XXX XX XX/XX/XX* *Edit View User Sort Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Sort* soft key.	Display output: Sort Methods By: Method name Date last used Date stored Method size Accept Cancel	**Yes** ☐ **No** ☐	
With the Circular key, highlight 'Date last used' and press *Accept* soft key.	Display output sorted by Date last used: *Methods User Size Last Used* *XXXX XXX XX XX/XX/XX* *XXXX XXX XX XX/XX/XX* *Edit View User Sort Cancel* Alternate Screen *Free Mem: XX methods XXX segments* *XXXX XXX XX XX/XX/XX* *XXXX XXX XX XX/XX/XX* *Edit View User Sort Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Sort* soft key.	Display output: Sort Methods By: Method Date Last used Date stored Method size Accept Cancel	**Yes** ☐ **No** ☐	
With the Circular key, highlight 'Date stored' and press *Accept* soft key.	Display output sorted by Date stored: *Methods User Size Stored* *XXXX XXX XX XX/XX/XX* *XXXX XXX XX XX/XX/XX* *Edit View User Sort Cancel* Alternate Screen *Free Mem: XX methods XXX segments* *XXXX XXX XX XX/XX/XX* *XXXX XXX XX XX/XX/XX* *Edit View User Sort Cancel*	**Yes** ☐ **No** ☐	
Press the *Sort* soft key.	Display output: Sort Methods By: Method Date last used Date stored Method size Accept Cancel	**Yes** ☐ **No** ☐	
With the Circular key, highlight 'Method size' and press *Accept* soft key.	Display output sorted by Method size: *Methods User Size Last Used* *XXXX XXX XX XX/XX/XX* *XXXX XXX XX XX/XX/XX* *Edit View User Sort Cancel* Alternate Screen *Free Mem: XX methods XXX segments* *XXXX XXX XX XX/XX/XX* *XXXX XXX XX XX/XX/XX* *Edit View User Sort Cancel*	**Yes** ☐ **No** ☐	

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Cancel* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *Name: XXXXX User: <<ab>>* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	

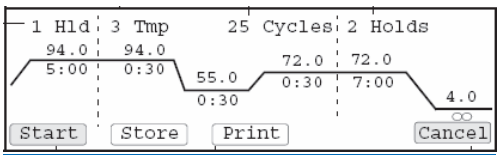
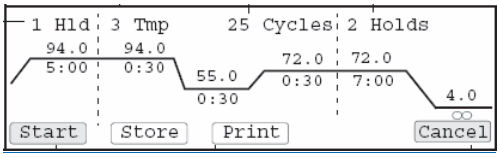
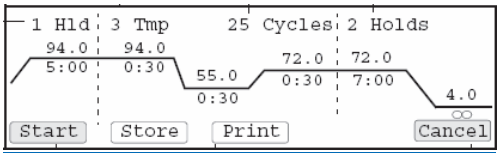
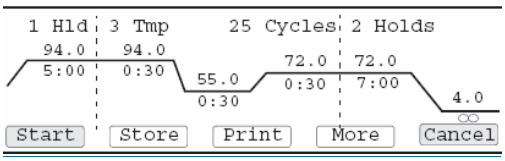
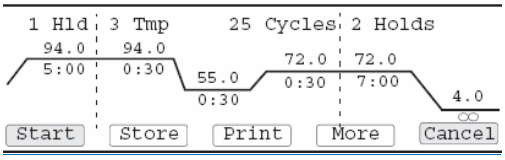
Exceptions:

Comments:

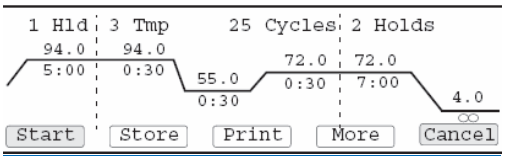
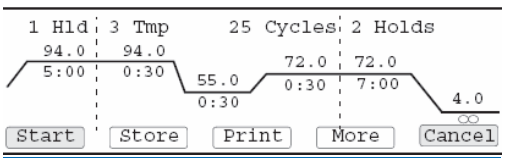
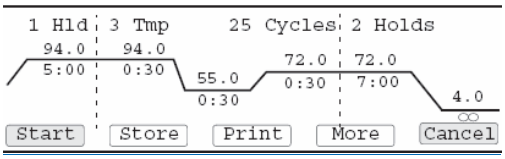
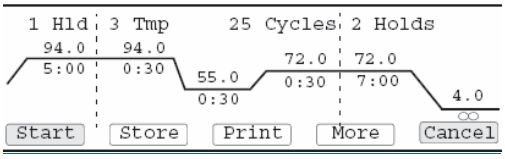
Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Edit* soft key two times in succession.	Display output: Thermal cycler test program  *F1* *F2* *F3* *F4* *F5*	**Yes** ☐ **No** ☐	
Using the key and circular keypad, highlight a test ‘temp’, input 3.9 then highlight another test ‘temp’.	Display output (5 seconds): Thermal cycler test program  *Valid range is 4.0 to 99.9*	**Yes** ☐ **No** ☐	
Using the key and circular keypads, highlight a test ‘temp’, attempt to input 100.0 then highlight another test ‘temp’.	Display output (5 seconds): Thermal cycler test program  *Valid range is 4.0 to 99.9*	**Yes** ☐ **No** ☐	
Using the key and circular keypad, highlight a test ‘temp’, input 25.0 then highlight another test ‘temp’.	Display output: Thermal cycler test program  *F1* *F2* *F3* *F4* *F5*	**Yes** ☐ **No** ☐	
Using the key and circular keypad, highlight a test ‘time’, input 0.0 then highlight another test ‘time’.	Display output: Thermal cycler test program  *F1* *F2* *F3* *F4* *F5*	**Yes** ☐ **No** ☐	

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Using the key and circular keypad, highlight a test 'time' in the cycle, input 99.00 then highlight another test 'time'.	Display output (5 seconds): Thermal cycler test program  *Infinity hold not allowed in cycle*	Yes ☐ No ☐	
Using the key and circular keypad, highlight a test 'time' in the cycle, input 99.99 then highlight another test 'time'.	Display output (5 seconds): Thermal cycler test program  *Seconds must be 0-59*	Yes ☐ No ☐	
Using the key and circular keypad, highlight a test 'time' in the cycle, input 98.59 then highlight another test 'time'.	Display output: Thermal cycler test program  *F1 F2 F3 F4 F5*	Yes ☐ No ☐	
Using the key and circular keypad, highlight a test 'time' in the **last** thermal cycler entry, input 99.00 then highlight a previous test 'time'.	Display output: Thermal cycler test program with ∞ as last time entry.  *F1 F2 F3 F4 F5*	Yes ☐ No ☐	
Press the *Cancel* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: xx* *Run Create Edit Util User*	Yes ☐ No ☐	

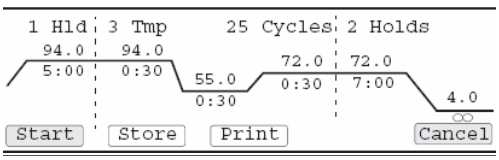
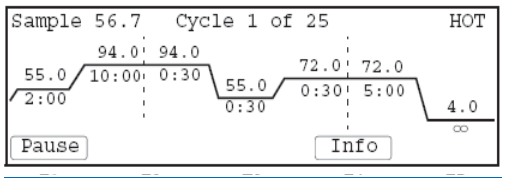
Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Create* soft key. .	Display output: Example Only  *F1* *F2* *F3* *F4* *F5*	**Yes** ☐ **No** ☐	
Press the Start soft key.	Display output: Select Method Options Reaction volume: 31 uL Ramp speed: HS96 or Std Run ID 1 Enter a value from 5 to 30 uL Start Cancel	**Yes** ☐ **No** ☐	
Please wait while the Heated cover heats up.	Display output: Please wait. Cover is heating. Current temperature: XXX°C The run will begin when the heated cover reaches 103°C. Cancel	**Yes** ☐ **No** ☐	
The Blinking line on the graphic indicates the method is running.	Display output: Example Only  *F1* *F2* *F3* *F4* *F5*	**Yes** ☐ **No** ☐	

10.3 Operation Qualification (continued)

Let the Method run for approximately 5 minutes. Press the *Stop* Key twice and Abort the run.	Display output (Temp. may be blinking): XX:XX XM End of Run XX.X C Method: XX Run completed at XX:XX:XX XM, XX/XX/XX. Length of run is XX:XX:XX. Hist Store Exit	**Yes** ☐ **No** ☐	
Press the *Hist* soft key.	Display output: History of method XXX User: XX Reaction volume: XuL Run started at XX:XX:XX XM XX/.XX/XX Run ended at XX:XX:XX XM XX/XX/XX Run Length: XX:XX:XX Ramp speed: 9600 No exceptions Print Return	**Yes** ☐ **No** ☐	
Press the *Return, Exit,* and *Exit* soft keys in succession.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: xx* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *User* soft key.	Display output: *Select User Name* *<<ab>> XXXX test1 test2 test3* *Accept New Edit Delete Cancel*	**Yes** ☐ **No** ☐	
Use the Circular Key to select 'test1' name and press *Accept* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: test1* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *User* soft key.	Display output: *Select User Name* *<<ab>> XXXX test1 test2 test3* *Accept New Edit Delete Cancel*	**Yes** ☐ **No** ☐	
Use the Circular Key to select 'test1' name and press *Delete* soft key.	Display output: *Select User Name* *<<ab>> XXXX test1 test2 test3* *Delete your methods first*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Wait 5 seconds for previous output screen to change.	Display output: Select User Name <<ab>> XXXX test1 test2 test3 .Accept New Edit Delete Cancel	**Yes** ☐ **No** ☐	
Press *Cancel Util More Delete* soft keys in succession.	Display output: *Methods User Size Stored* *XXXX test1 X XX/XX/XX* *Delete View User Sort Cancel* Alternate Screen *Free Mem: XX methods XXX segments* *XXXX test1 X XX/XX/XX* *Delete View User Sort Cancel*	**Yes** ☐ **No** ☐	
Press the *Delete* soft key.	Display output: Security Check To perform this action, you must enter you PIN number. Your PIN #: Delete Cancel	**Yes** ☐ **No** ☐	
Enter PIN # 123 with key tab and press the *Accept* soft key. Press *Yes* to Delete method.	Display output: Delete Method Methods User Size Stored XXX test1 X XX/XX/XX Press Yes to delete the method Yes Cancel	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Cancel* soft key.	Display output: *Methods User Size Stored* *XXXX test1 X XX/XX/XX* *Delete View User Sort Cancel* Alternate Screen *Free Mem: XX methods XXX segments* *XXXX test1 X XX/XX/XX* *Delete View User Sort Cancel*	**Yes** ☐ **No** ☐	
Press *Delete* soft key.	Display output: Security Check To perform this action, you must enter you PIN number Your PIN #: Accept Cancel	**Yes** ☐ **No** ☐	
Enter PIN # 123 with key tab and press the *Accept* soft key.	Display output: Delete Method Methods User Size Stored XXX test1 X XX/XX/XX Press Yes to delete the method Yes Cancel	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Yes* soft key.	Display output: *No Methods* *User* *Cancel*	**Yes** ☐ **No** ☐	
Press the *Cancel* soft key.	Display output: Utilities Delete – Delete a method Copy – Copy methods from/to PC card Hist – Display history of last run Delete Copy Hist More Exit	**Yes** ☐ **No** ☐	
Press the *Exit* soft key.	Display output: *Time* *Date* *Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: test1* *Run* *Create* *Edit* *Util* *User*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *User* soft key.	Display output: Select User Name <<ab>> XXX test1 test2 test3 Accept New Edit Delete Cancel	**Yes** ☐ **No** ☐	
Use the Circular Key to select 'test1' name and press *Accept* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: test1* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press *User* then *Delete* soft keys.	Display output: Select User Name <<ab>> XXX test2 test3 Accept New Edit Delete Cancel	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Cancel* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: xx* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *User* soft key.	Display output: *Select User Name* *<<ab>> XXXX test2 test3* *Accept New Edit Delete Cancel*	**Yes** ☐ **No** ☐	
Use the Circular Key to select 'test2' name and press *Accept* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: test2* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press *Util More Delete* soft keys in succession.	Display output: *Methods User Size Stored* *XXXX test2 X XX/XX/XX* *Delete View User Sort Cancel* Alternate Screen *Free Mem: XX methods XXX segments* *XXXX test2 X XX/XX/XX* *Delete View User Sort Cancel*	**Yes** ☐ **No** ☐	
Press the *Delete* soft key.	Display output: Delete Method Methods User Size Stored XXX test2 X XX/XX/XX Press Yes to delete the method Yes Cancel	**Yes** ☐ **No** ☐	
Press the *Yes* soft key.	Display output: *No Methods* *User Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Cancel* soft key.	Display output: Utilities Delete – Delete a method Copy – Copy methods from/to PC card Hist – Display history of last run Delete Copy Hist More Exit	**Yes** ☐ **No** ☐	
Press the *Exit* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: test2* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *User* soft key.	Display output: Select User Name <<ab>> XXX test2 test3 Accept New Edit Delete Cancel	**Yes** ☐ **No** ☐	
Use the Circular Key to select 'test2' name and press *Delete* soft key.	Display output: Select User Name <<ab>> XXX test3 Accept New Edit Delete Cancel	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Cancel* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: xx* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *User* soft key, highlight 'test3' with the Circular Key and press the *Accept* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: test3* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press *Util More Delete* soft keys in succession.	Display output: *Methods User Size Stored* *XXXX test3 X XX/XX/XX* *Delete View User Sort Cancel* Alternate Screen *Free Mem: XX methods XXX segments* *XXXX test3 X XX/XX/XX* *Delete View User Sort Cancel*	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Delete* soft key.	Display output: Delete Method Methods User Size Stored XXX test3 X XX/XX/XX Press Yes to delete the method Yes Cancel	**Yes** ☐ **No** ☐	
Press the *Yes* soft key.	Display output: *No Methods* *User* *Cancel*	**Yes** ☐ **No** ☐	
Press the *Cancel* soft key.	Display output: Utilities Delete – Delete a method Copy – Copy methods from/to PC card Hist – Display history of last run Delete Copy Hist More Exit	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Press the *Exit* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: xx* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *User* soft key; use the Circular Key to select '<<ab>>' name and press *Accept* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: <<ab>>* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *Run* soft key, highlight 'AmpliTaq Gold' method with the Circular Key, and press the *Start* soft key two times in succession.	Display output (HOT may be blinking): *Sample XXX* Thermal cycler test program running *Pause Info*	**Yes** ☐ **No** ☐	
Disconnect the power cord from the power source (or turn the instrument OFF).	Display output: Screen goes blank and power light goes OFF.	**Yes** ☐ **No** ☐ Time OFF: _____	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
Reconnect the power source to the instrument (or turn the instrument ON) at >15 seconds and <3 minutes after power loss.	Power light is ON (red) and instrument starts up. Display output: The instrument determines what thermal cycler temperature was being approached or was holding and upon resumption of power the program will go to the temperature and countdown the time remaining in the hold as soon as the temperature is within the specified clock start limits.	**Yes** ☐ **No** ☐ Time ON: _____	
Press the STOP keypad key twice and then the *Exit* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: xx* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *Util* soft key and log the time.	Display output: *Utilities* *Diag – Instrument diagnostics* *TmCalc – Calculates melting temp* *Config – Instrument configuration* *Diag TmCalc Config More Exit*	**Yes** ☐ **No** ☐ Time: _____	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.3 Operation Qualification (continued)

Input	Expected Output	Acceptable Yes/No	Initials/Date
After 15 minutes from the pressing of the *Util* soft key, the screen goes OFF.	Display output: Screen is OFF (blank).	**Yes** ☐ **No** ☐ Time: _____	
Press any button on the keypad or circular key.	Display output of last screen before 'screen saver' mode is activated: *Utilities* *Diag – Instrument diagnostics* *TmCalc – Calculates melting temp* *Config – Instrument configuration* *Diag TmCalc Config More Exit*	**Yes** ☐ **No** ☐	
Press the *Exit* soft key.	Display output: *Time Date Temp. C* *Applied Biosystems 9800 System* *Version: X.XX* *User: <<ab>>* *Run Create Edit Util User*	**Yes** ☐ **No** ☐	
Press the *Run* soft key, highlight 'AmpliTaq Gold' method with the Circular Key, and press the *Start* soft key two times in succession.	Display output (HOT may be blinking): *Sample XXX* Thermal cycler test program running *Pause Info*	**Yes** ☐ **No** ☐	
Let the 'AmpliTaq Gold' cycle run to 4 C hold. Press the STOP key twice to abort the run.	Display output (temperature may be blinking): XX:XX XM End of Run XX.X C Method: XX Run completed at XX: XX: XX XM, XX/XX/XX. Length of run is XX: XX: XX. Hist Store Exit	**Yes** ☐ **No** ☐	
Press the power OFF key.	Screen goes blank and power light goes OFF.	**Yes** ☐ **No** ☐	

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

10.4 Customer Familiarization Verification

Perform and document the verification activities listed below.

	Activity	Method*		
		V	D	T
1.	Verify that users have completed training on the operation of the Applied Biosystems 9800 FAST Thermal Cycler after installation of the system. Attach documentation of the training to the envelope at the back of the IQ/OQ binder, if available.			

Exceptions:

Comments:

Acceptance Criteria: The results of the above activities have been verified and are acceptable.

Conducted By Signature:_____Date:_____

Customer Signature: _____Date:_____

* V = Visually verified
D = Certification/documentation reviewed and visually verified
T = Tested and deemed acceptable
All verifications are reviewed and visually verified by the individual who signs the "EXECUTED By: Signature" section above.

11 IQ/OQ Report and Protocol Final Approval

Review and approve according to the procedures and quality system requirements of the organization that owns the instrument.

The completion of the Final Approval signatures indicates acceptance that the Applied Biosystems 9800 FAST Thermal Cycler Installation Qualification/Operation Qualification Protocol has been executed in full.

Initial and date one of the following:

_____ The Applied Biosystems 9800 FAST Thermal Cycler Instrument Performance Verification Protocol was completed without exceptions.

_____ The Applied Biosystems 9800 FAST Thermal Cycler Instrument Performance Verification Protocol was completed with exceptions noted in the following section numbers:

Section numbers: _____

_____

_____

_____

_____

_____

Final Approval:

Print Name	Protocol Executed By Signature	Title	Date
Print Name	Results Confirmed By Signature	Title	Date
Print Name	Customer Signature	Title	Date
Print Name	Customer Signature	Title	Date

This page is intentionally blank.

This page is intentionally blank.