

SOP Title: **Operation of C1000 Touch Thermal Cyclcr**

SOP Number: **23013**

Revision: **00**

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1. PURPOSE

The purpose of this SOP is to outline the proper procedures for operating the C1000 Touch Thermal Cyclcr.

2. SCOPE

This SOP applies to Biopharmaceutical Development Program (BDP) personnel operating and maintaining the C1000 touch thermal cyclcr. This SOP describes the procedures used for the basic operation and maintenance of the multi-component C1000 Touch Thermal cyclcr.

The Thermal cyclcr (or Thermocyclcr) is used for PCR (Polymerase chain reaction) based assays to amplify segments of DNA (Deoxyribonucleic acid) by raising and lowering the temperature of the reaction mix in a pre-programmed step.

3. RESPONSIBILITIES

3.1 Director, Process Analytics/Quality Control (PA/QC)

- Defines this procedure.

3.2 Process Analytics/Quality Control PA/QC

- Performs the procedure.
- Reviews the data and documentation of the results of this procedure.

3.3 BQA

- Provides quality oversight of this operation.

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4. SAFETY

Do not open the thermal cyclers lid while the heating block is hot to avoid the risk of burns.

5. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
22682	PCR Single Tubes	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
22679	PCR 8 Strip Tubes	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
22678	PCR 8 Strip caps	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
22673	ddPCR 96 well plates	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
21141	96 well optical plates	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

5.1 Specific reagents and samples will be indicated in assay-specific SOPs and recorded on the SOP-specific Forms.

6. EQUIPMENT

- C1000 Touch Thermal Cyclers (Deep Well), MEF# 88070.

7. PROCEDURE

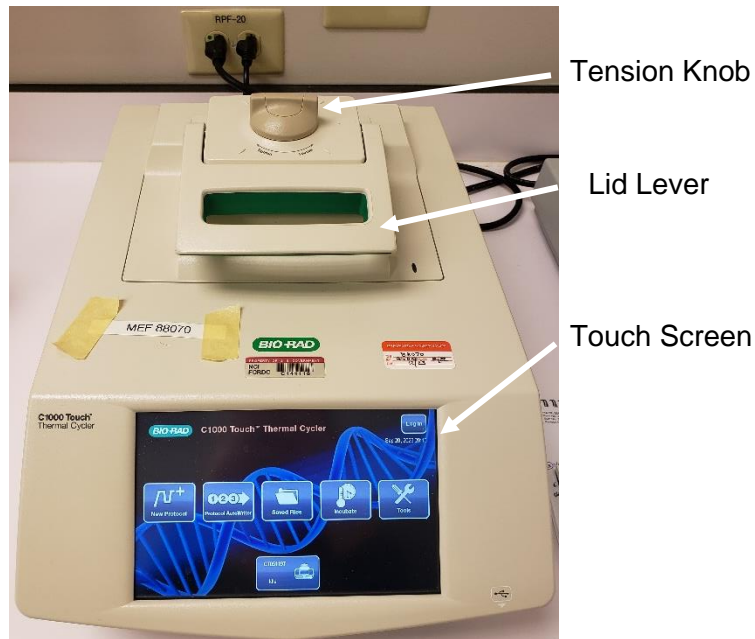
7.1 Powering On:

7.1.1 Ensure that the C1000 Thermal Cyclers is plugged in.

7.1.2 Push the power switch at the back of the instrument and wait for the touch screen display to initialize. Address any error messages before running the program.

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7.2 Loading the instrument



- 7.2.1 Open the lid by slightly unscrewing the Tension knob counterclockwise and then lifting up on the lid lever. The lid will slide back slightly before opening.
- 7.2.2 Seat the individual capped tubes, or sealed plate into the circular metal wells.
 - 7.2.2.1 If using individual tubes, distribute them evenly across the wells.
 - 7.2.2.2 Make sure tubes are completely sealed, or you may lose reagent volume during the run.
- 7.2.3 Close the lid and bring down the lid lever. Turn the Tension knob clockwise until there is slight resistance, then continue for half a turn.

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7.3 Running a Saved Protocol



NOTE: Thermal Cycler protocols for standard assays will be described in their individual SOPs. Please review the specific SOP you are using and compare it to any saved program before running.

7.3.1 Touch the **Saved Files** button.

7.3.2 Touch to navigate to the correct folder. Most programs will appear in Recent -> <Root>. You can scroll up and down by tapping the arrows to view more Files.



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7.3.3 To view or edit a protocol before running it, select the protocol and then select **Edit**.

7.3.4 If the protocol is correct, select **Run** to run the protocol. If the protocol needs to be updated, refer to section 7.5 to edit and save the protocol before running.

7.3.4.1 A popup will appear to adjust the Volume and Lid Temp. When you have selected the correct Volume and Temp, touch **OK** and the protocol will start.

NOTE: The standard lid temperature is 105°C. This can be changed if an individual SOP specifies a different temperature.

7.3.5 The Screen will display the protocol with the remaining time at the top. You can select **View Clock** to display the countdown only.

NOTE: Do not open the lid until the run has completed.

NOTE: If you are ending in an infinite hold at low temperatures, do not leave the machine running for more than 24 hours. Extended holds at low temperature can create condensation and damage the Thermal Cycler.

7.4 Finishing a Run

7.4.1 When the run has completed it will display 00:00:00 as the time remaining, or if an infinite hold has been selected, it will display Infinite Hold as the time remaining.

7.4.1.1 To end an infinite hold, touch **Cancel**. Wait until the run appears as canceled before unloading or starting a new run.

7.4.1.2 Touch the **Home** button to select another protocol, or to leave the instrument ready for the next user.

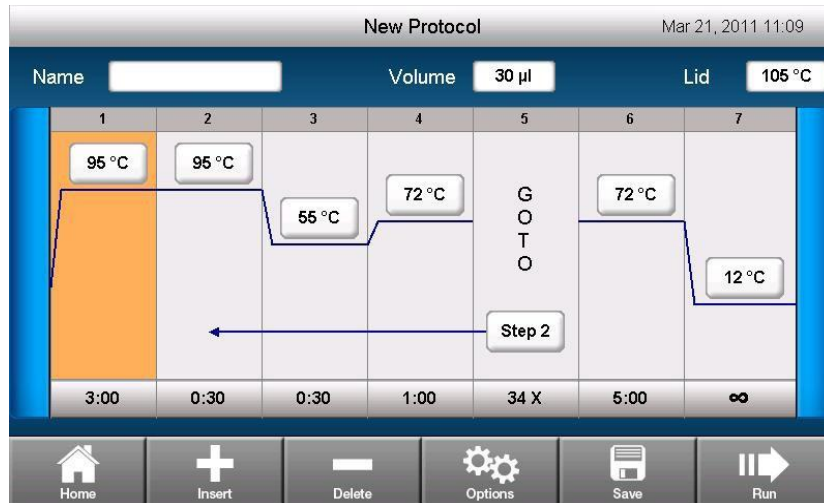
7.4.1.3 It is not necessary to turn the thermal cycler switch to off.

7.4.2 To unload the thermal cycler, turn the Tension knob counterclockwise at least one full turn and lift up on the lid lever.

7.4.2.1 Remove all tubes or plate from the thermal cycler and close the lid, but do not press down the lid lever.

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7.5 Creating and Editing a Program



- 7.5.1 From the Home screen touch **New Protocol**. A template protocol will appear.
- 7.5.2 At the top of the screen you can edit the **Name**, **Volume**, and **Lid** temperature by touching the white box and typing in the correct values.
- 7.5.3 To change the times or temperatures for any step, touch the value you want to edit, then use the number pad to enter the correct value. Touch **OK** to save.
- 7.5.3.1 Times are displayed as MM:SS
- 7.5.3.2 You can add a ramp rate to temperature steps by touching the step to select, then touching the **Options** button and selecting the **Ramp Rate** box to enter the desired value.
- 7.5.4 To delete a step, touch the step to be deleted and then touch the **Delete** button.
- 7.5.5 To insert a step, touch the step to the left of the one to be added and touch **Insert**. You will be prompted to select the type of step: Temperature, GOTO, or Gradient.

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- 7.5.5.1 A temperature step can be edited by selecting the step, **Options**, and entering the values for temperature and time or by directly selecting the temperature and time.
- 7.5.5.2 A GOTO step can be edited by selecting the step, **Options**, and selecting the step to return to, and the number of times to repeat.
- 7.5.5.3 A Gradient step can be edited by selecting the step, **Options**, and touching the upper and lower temperatures to adjust or by touching a temperature step and selecting the “Gradient” check box and adjusting the upper and lower temperatures.

NOTE: A gradient range must be between 1 and 24°C.

NOTE: A gradient step can also include an Extend parameter but cannot include parameters such as Increment, Beep, or Ramp Rate.



- 7.5.6 If you wish to end the program with an infinite hold, touch the last step, then the time box, then select the ∞ symbol and **OK**.
- 7.5.7 When you have the protocol entered as desired touch **Save** and choose the location where you would like to save the protocol.

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8. DOCUMENTATION AND RECORDS

8.1 Record all work performed in equipment logbook according to SOP 21531 for equipment logs.

8.2 MEF number and calibration due date should be recorded on the assay-specific forms for whatever assay is being performed.

9. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
N/A	C1000 Touch Thermal Cycler Instruction Manual
21531	Equipment Logs