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PURPOSE

1.1. The purpose of this procedure is to set instructions in the proper use and maintenance of a Thermomixer.

2. SCOPE

2.1. This procedure applies to all Thermomixers.

3. REFERENCES

3.1. Thomas Scientific Thermal Mixer User Manual

3.2. Eppendorf ThermoMixer User Manual

3.3. 10007: Non-Routine Equipment Maintenance

3.4. 10009: General Record Review

3.5. 26010-01: Thermomixer Maintenance Form

4. RESPONSIBILITIES

4.1. The Research Associate, hereafter referred to as Analyst, is responsible for reviewing and following this procedure, and documenting performance of equipment maintenance.

4.2. The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.

4.3. The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.

4.4. Trained personnel perform equipment maintenance record review per “10009: General Record Review.”

5. DEFINITIONS

5.1. As Needed Maintenance – Maintenance that is performed outside of routine maintenance but is not performed in response to equipment malfunction.

5.2. Non-Routine Maintenance – Maintenance that is performed in response to equipment malfunction or failure.

5.3. Routine Maintenance – Maintenance that is performed at planned intervals to identify and prevent problems before they result in equipment failure.

6. REAGENTS, CHEMICALS, AND EQUIPMENT

6.1. Block for 24 x 2.0 mL Microtubes

6.2. Block for 96-well PCR Microplate

6.3. Primary Disinfectant (Cavicide, FNLCR Warehouse, Cat # 79300360 or equivalent)

6.4. Thermo Mixer (Thermo Scientific or Eppendorf)

6.5. Thermometer, National Institute of Standards and Technology (NIST Traceable (VWR, Cat # 10171-388 or equivalent)

6.6. Wipe, Low-Lint, Wypalls (FNLCR Warehouse, Cat # 79300335 or equivalent)

7. HEALTH AND SAFETY CONSIDERATIONS

7.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.

7.2. Refer to the respective Safety Data Sheet (SDS) when working with any chemicals.

7.3. Refer to “HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility,” “EHS-WM-1: Disposal and Minimization of Chemical Waste,” and “EHS-WM-2: Biological Waste Handling and Disposal” for waste disposal processes.

7.4. Do not check Thermo Mixer temperature by touch. Use a Thermometer.

8. PROCEDURE PRINCIPLES

8.1. Do not allow items to impede platform motion when Thermo Mixer is rotating.

8.2. Place Thermo Mixer on flat, non-flammable surface.

8.3. Ensure Tubes and Microplates are Thermo resistant before using in Thermo Mixer.

8.4. When Lid is removed from Thermo Mixer, platform and Lid heating surfaces will remain hot.

8.5. After Analyst is finished using Thermo Mixer, turn Power Switch at the back of the unit off and unplug it.

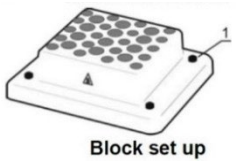
9. BLOCK INSTALLATION

9.1. Thermo Scientific

9.1.1. Turn OFF unit and disconnect external power supply.

9.1.2. Remove the four knurled screws (see Image 1).

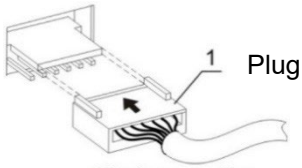
Image 1: Block set up



Block set up

9.1.3. Lift block without damaging the cable and disconnect plug (see Image 2).

Image 2: Plug and Contact Terminal (Underside of Block)



Plug and Contact terminal

Block connection

9.1.4. Choose appropriate block (96-well PCR microplate, 2.0 mL microtubes) and connect plug to the contact terminal. Use Figure 2 as a guide. Ensure connector is mounted tightly.

9.1.5. Align block so warning labels (hot) are facing the front of unit.

9.1.6. Secure with the four knurled screws from step 8.2. Use Image 2 as a guide.

9.1.7. Insert digital thermometer probe into a micro centrifuge tube (1.5 – 2.0 mL tube) with a thermostable matrix when using block for 2.0 mL microtubes, or in a single PCR block cup when using 96-well PCR microplate block. Block is ready for use as soon as temperature reading from digital thermometer probe is at desired temperature.

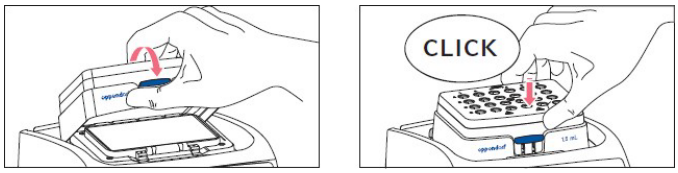
9.2. Eppendorf

9.2.1. First, place rear section of block attachment on rear section of unit.

9.2.2. Then, lower front section of block attachment onto unit until an audible click is heard.

Note: The block must be oriented with block name printing towards the front of the instrument.

Image 3. Eppendorf Block Attachment



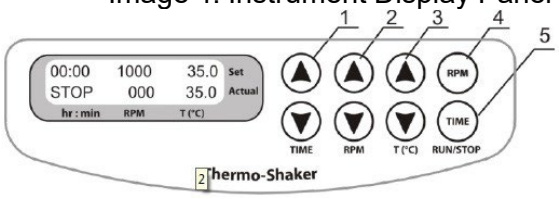
9.2.3. To remove thermoblock from unit, press down on the front blue tab on thermoblock, and raise front end of the thermoblock.

9.2.4. Finally, raise rear section of thermo block and remove device.

10. EQUIPMENT USE

10.1. Setting Control Panel Parameters

Image 4: Instrument Display Panel



10.1.1. **Setting time (TIME).** Using the ▲and ▼ **TIME** button set the required working time interval in hours and minutes (increment 1 min). Pressing the button for more than 3 seconds will increase the increment rate.

10.1.2. **Setting speed (RPM).** Using the ▲and ▼ **RPM** button set the required speed (increment 10 rpm). Pressing the button for more than 3 seconds will increase the increment rate.

10.1.3. **Setting temperature (T, ºC).** Using the ▲and ▼ **T, ºC** button set the necessary temperature (increment 0.1°C). Pressing the button for more than 3 seconds will increase the increment rate.

10.2. Pre-Heat incubator block prior to use.

10.2.1. Turn Thermomixer on and select Program parameters, step 9.1.

10.2.2. Thermomixer will immediately begin heating Block to desired temperature.

10.3. Once Thermomixer has reached programmed temperature, add samples.

10.3.1. If Program includes rotation, ensure samples are balanced within Block.

10.4. Press **RPM-RUN/STOP**. The platform will start rotating and the timer indicator will start counting up the time interval (with 1 min precision).

Note: If the rotation speed is set to zero, pressing **RPM-RUN/STOP** will start the timer but the platform will not move.

10.5. After Program completion (after set time elapses), platform motion will stop and timer will flash “STOP” accompanied by a repetitive sound.

10.6. Press **RPM-RUN/STOP** to quiet alarm.

10.7. If working time is not set (or is reset) and timer indicator in upper line shows 00:00, pressing **RPM-RUN/STOP** will start continuous operation of device with countdown timer in lower line (Actual) until **RPM-RUN/STOP** is pressed again.

10.8. If required, there is the possibility to restart the timer when it is running. Press **TIME-RUN/STOP** once to stop the timer. Press **TIME-RUN/STOP** again to restart the timer.

10.9. The platform motion can be stopped at any time by pressing **RPM-RUN/STOP**. In this case the Program and the platform motion will pause and the timer will switch into the STOP mode, saving previously set time. Press **RPM-RUN/STOP** to repeat the operation with the same time and speed.

10.10. Once completed turn the Power Switch, located on the rear panel of the unit, in position O (Off) and disconnect the power cord from electric circuit.

10.11. Eppendorf

10.11.1. Setting Control Panel Parameters

Image 5. Instrument Display Panel

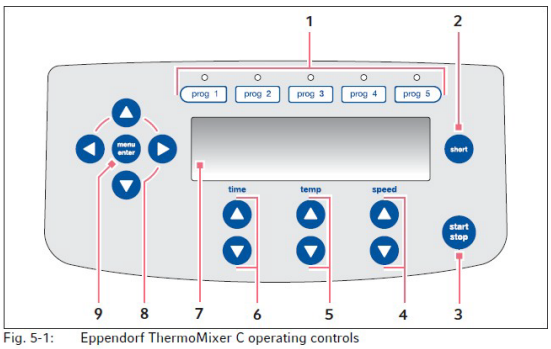


Fig. 5-1: Eppendorf ThermoMixer C operating controls

1 **Program keys with control LEDs**
2 **short key**
Short Mix will run as long as the **short** key is pressed.
3 **start/stop key**
Press the **start/stop** key: Start or stop mixing/temperature control
4 **speed arrow keys**
Setting the mixing frequency
5 **temp arrow keys**
Setting the temperature
6 **time arrow keys**
Setting the mixing time
7 **Display**
8 **Menu arrow keys**
Navigating in the menu
9 **menu/enter key**
Open the menu
Confirm your selection

10.11.1.1. **Setting time (TIME).** Using the ▲and ▼ **TIME** button set the required working time interval in hours and minutes (increment 1 min).

10.11.1.2. **Setting speed (SPEED).** Using the ▲and ▼ **SPEED** button set the required speed (increment 10 rpm).

10.11.1.3. **Setting temperature (TEMP).** Using the ▲and ▼ **TEMP** button set the necessary temperature (increment 0.1°C).

11. MAINTENANCE

11.1. Semi-Annual Temperature Verification

Note: Twice a year, verify the temperature of the thermoblock at 20°C and 95°C with a NIST thermometer.

11.1.1. Set the temperature of the instrument to 20°C, wait 5 minutes after reaching desired temperature to add the NIST thermometer. After 5 minutes, record the temperature of the instrument and thermometer on form 26010-01.

11.1.2. Repeat 11.1.1 at 95°C.

11.1.3. The allowable temperature difference between the instrument and NIST thermometer is ± 1°C. If the temperature exceeds the allowable limit, then start the Non-Routine Maintenance procedure (see section 11.4).

11.2. Annual Maintenance

11.2.1. Cleaning

11.2.1.1. Spray Low-Lint Wipe with Cavicide and wipe Thermomixer and Block. Wait 3 minutes.

11.2.1.2. Spray Low-Lint Wipe with Ster-ahol or 70% Alcohol and wipe Thermomixer and Block.

11.2.1.3. Once dry, Thermomixer is ready for reassemble and use as needed.

11.2.1.4. Document cleaning on “26010-01 Thermomixer Maintenance Form.”

11.3. As Needed Maintenance

Note: Document As Needed Maintenance in its respective section on form 26010-01.

11.3.1. Cleaning

11.3.1.1. If spill occurs or if heat block becomes visibly soiled, unplug unit and wait for it to reach Room Temperature,

11.3.1.2. Spray Low-Lint Wipe with Cavicide and wipe Thermomixer and Block. Wait 3 minutes.

11.3.1.3. Spray Low-Lint Wipe with Ster-ahol or 70% Alcohol and wipe Thermomixer and Block.

11.3.1.4. Once dry, Thermomixer is ready for reassemble and use as needed.

11.3.1.5. Document cleaning on 26010-01 form.

11.4. Non-Routine Maintenance

11.4.1. In the case that Thermomixer is not operating correctly, transition processes being performed to another unit (when applicable), post a sign stating the equipment is out of service and initiate non-routine maintenance documentation per "10007: Non-Routine Equipment Maintenance."

11.4.2. Document the nature of any failures or malfunctions, how and when it was discovered, and the personnel involved on "10007-01: Non-Routine Equipment Maintenance Form."

11.4.3. Initiate a service request and complete the non-routine maintenance process following 10007.

12. SETTINGS

12.1. Temperature: 4°C – 100°C

13. ATTACHMENTS

13.1. Attachment 1: 26010-01: Thermomixer Maintenance Form

Frederick National Laboratory for Cancer Research
sponsored by the National Cancer Institute

HPV Serology Laboratory
Standard Operating Procedure
Form

Form Title: Thermal Mixer Maintenance Form

Document ID: 26010-01	Version:	4.0
Associated SOP: 26010	Effective Date:	12Aug21
Supersedes Version: New	**Page 1 of 2**	

Equipment ID:		Maintenance Year:	

Annual Maintenance

Performed by/ date	Cleaning Agent	Cleaning Agent Lot Number	Cleaning Agent Expiration Date	Reviewed by/ Date
	□ Cavicide □ Other:			
	□ Ster-ahol □ Other:			

Semi-Annual Temperature Verification

Performed by/ date	Temperature	Actual Instrument Reading	Actual NIST Thermometer Reading	Pass/Fail (±1°C)	Reviewed by/ Date
	20°C			□ Pass □ Fail	
	95°C			□ Pass □ Fail	

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Frederick National Laboratory for Cancer Research
sponsored by the National Cancer Institute

HPV Serology Laboratory
Standard Operating Procedure
Form

Form Title: Thermal Mixer Maintenance Form

Document ID: 26010-01		Version:	4.0
Associated SOP: 26010		Effective Date:	12Aug21
Supersedes Version:	New	**Page 2 of 2**	

As Needed Maintenance: ☐ N/A

Date	Activity Performed	Recorded by/date	Reviewed by/date
☐ N/A			
☐ N/A			

QA Reviewed by/date: _____

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14. REVISION HISTORY

Date Changed	Version #	Changes	Reasons
15Mar17	1.0	Create new SOP for the use and maintenance of the Thermo mixer	New SOP.
05Dec19	2.0	Editing	Clarity/Ease of use
04Aug21	3.0	Add updated Maintenance guidance	Following GDP Guidance