

<b>Frederick National Laboratory for Cancer Research</b> <small>sponsored by the National Cancer Institute</small>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Forma Scientific Orbital Shaker		
<b>Document ID: HSL_EQ_011</b>	Version 1.0	Page 1 of 8

Released by/Date Effective:

---

Author Name	Title	Signature/Date
Casper Alabanza	Research Associate II	

Approver Name	Title	Signature/Date
Troy Kemp	Scientific Manager	
Christine Newkirk	QA Specialist III	

Use of a superseded or obsolete document is prohibited.  
 Users must ensure document is current prior to each use.

This document contains confidential and proprietary information.  
 Do not copy or distribute without prior, written permission.

<p><b>Frederick National Laboratory for Cancer Research</b> <i>sponsored by the National Cancer Institute</i></p>	<p>HPV Serology Laboratory Standard Operating Procedure</p>	
<p>Use and Maintenance of the Forma Scientific Orbital Shaker</p>		
<p>Document ID: HSL_EQ_011</p>	<p>Version 1.0</p>	<p>Page 2 of 8</p>

**1. PURPOSE**

- 1.1. The purpose of this procedure is to describe the proper use and maintenance of the Forma Scientific Orbital Shaker.

**2. SCOPE**

- 2.1. This procedure applies to the HPV Serology Laboratory located at the Advanced Technology Research Facility, Room C2007.

**3. REFERENCES**

- 3.1. Forma Scientific Orbital Shaker Model 4535 user manual
- 3.2. HSL\_EQ\_011.01: Orbital Shaker Use and Maintenance Form
- 3.3. HSL\_GL\_001: Waste Disposal at the Advanced Technology Research Facility
- 3.4. HSL\_GL\_002: Equipment Qualification and Calibration in the HPV Serology Laboratory
- 3.5. HSL\_GL\_003: Good Documentation Practices for the HPV Serology Laboratory
- 3.6. HSL\_GL\_006: Reagent Preparation for the HPV Serology Laboratory
- 3.7. HSL\_GL\_007: Reagent and Chemical Expiry in the HPV Serology Laboratory
- 3.8. HSL\_GL\_008: Laboratory Flow and Gowning Procedures for the HPV Serology Laboratory
- 3.9. HSL\_GL\_009: HPV Serology Laboratory BSL-2 Procedures
- 3.10. HSL\_GL\_010: Control and Request of Documents in the HPV Serology Laboratory

**4. RESPONSIBILITIES**

- 4.1. The Research Associate, hereafter referred to as analyst, is responsible for reviewing and following this procedure.
- 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.

**5. REAGENTS, CHEMICALS AND EQUIPMENT**

- 5.1. Forma Scientific Orbital Shaker (Model # 4535)

<b>Frederick National Laboratory for Cancer Research</b> <small>sponsored by the National Cancer Institute</small>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Forma Scientific Orbital Shaker		
<b>Document ID: HSL_EQ_011</b>	Version 1.0	Page 3 of 8

- 5.2. HEPA Filter (Thermo Scientific, Cat # 760164 or equivalent)
- 5.3. Cavicide (Warehouse, Cat # 79300360)
- 5.4. Ster-ahol (VWR, Cat # 14003-358 or equivalent)
- 5.5. Wypalls paper towel (Warehouse, Cat # 79300335 or equivalent)
- 5.6. Thermometer, NIST traceable (VWR, Cat # 89495-974 or equivalent)

## 6. HEALTH AND SAFETY CONSIDERATIONS

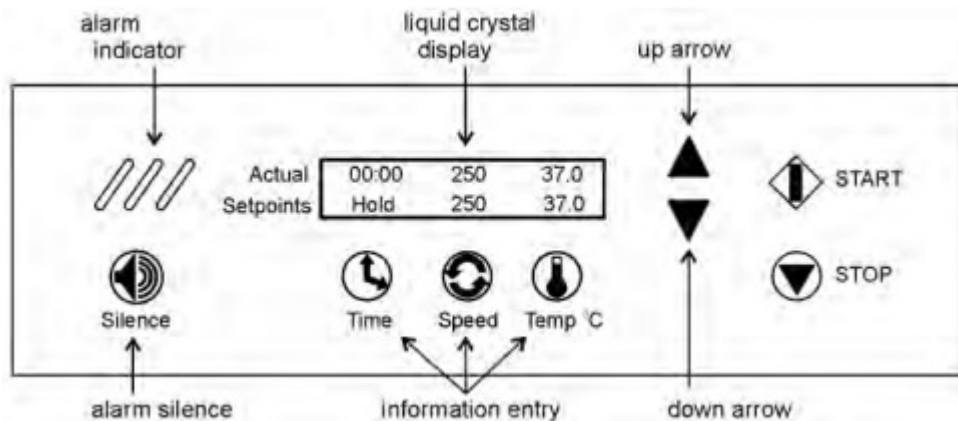
- 6.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.
- 6.2. Refer to the respective SDS when working with any chemicals.
- 6.3. Refer to "HSL\_GL\_001: Waste Disposal at the Advanced Technology Research Facility" regarding waste disposal processes at the ATRF.

## 7. DEFINITIONS

Term	Definition
ATRF	Advanced Technology Research Facility
HPV	Human Papillomavirus
HSL	HPV Serology Laboratory
SDS	Safety Data Sheets
SOP	Standard Operating Procedure

## 8. OPERATION

- 8.1. Control panel overview:



<p><b>Frederick National Laboratory for Cancer Research</b> <i>sponsored by the National Cancer Institute</i></p>	<p>HPV Serology Laboratory Standard Operating Procedure</p>	
<p>Use and Maintenance of the Forma Scientific Orbital Shaker</p>		
<p>Document ID: HSL_EQ_011</p>	<p>Version 1.0</p>	<p>Page 4 of 8</p>

## 8.2. Setting Temperature, Speed, Time Settings

### 8.2.1. Setting Temperature

- 8.2.1.1. Press the button beneath the temperature set-point (Temp °C). The temperature value will begin to flash.
- 8.2.1.2. Press the up or down arrows to set the new temperature in 0.1°C increments. Hold either button to scroll.
- 8.2.1.3. Press the temperature button again to return to the Operating Screen.

### 8.2.2. Setting RPM

- 8.2.2.1. Press the button beneath the Speed set-point. The RPM value will begin to flash.
- 8.2.2.2. Press the up or down arrows to set the new speed in 1 RPM increments. Hold either button to scroll.
- 8.2.2.3. Press the Speed button again to return to the Operating Screen.

### 8.2.3. Setting Time (from Hold to Countdown)

- 8.2.3.1. **Hold** - When Time is set to Hold, the value shown in the Actual portion of the display represents total operating time and may be reset at the operator's convenience. The shaker will continue to count upwards even if the console lid has been repeatedly opened and closed, or turned off and on with the power switch. The Time will, however, reset to 00:00 when the Stop button is pressed and the unit then restarted by pressing the Start button.
- 8.2.3.2. **Countdown** - When the Hold set-point is changed to Countdown entering a time value in hours and minutes, the shaker will operate for that period and automatically shut down. The display will show the total time in the Set-point segment and the operating time remaining in the Actual part of the display, as the microprocessor counts down to zero.
- 8.2.3.3. Press the button beneath the Time set-point. Hold will begin to flash.
- 8.2.3.4. Press either arrow to access the Countdown Time set-point. The preset time set-point will begin to flash.

<p><b>Frederick National Laboratory for Cancer Research</b> <i>sponsored by the National Cancer Institute</i></p>	<p>HPV Serology Laboratory Standard Operating Procedure</p>	
<p>Use and Maintenance of the Forma Scientific Orbital Shaker</p>		
<p>Document ID: HSL_EQ_011</p>	<p>Version 1.0</p>	<p>Page 5 of 8</p>

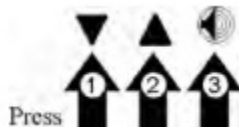
8.2.3.5. Press the up or down arrows to set the desired operating time in five minute increments. Hold either arrow to scroll in that direction.

8.2.3.6. When the desired elapsed time is set (8 hours, 30 minutes in this example), press the Time button to return to the Operating Screen. Pressing the Start button will start the shaker and begin the countdown sequence. When 00:00 is reached, the shaker will automatically shut off and the Cycle Complete alarm will sound.

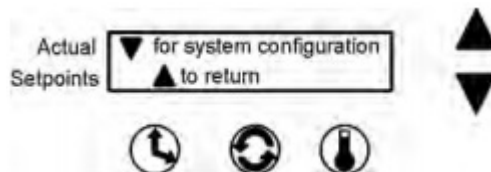
## 9. SYSTEM CALIBRATION

### 9.1. Calibrate Shaker Speed (RPM)

9.1.1. From the Operating screen, press the down arrow, up arrow and Silence button in that sequence (shown below) to open the Configuration menu.

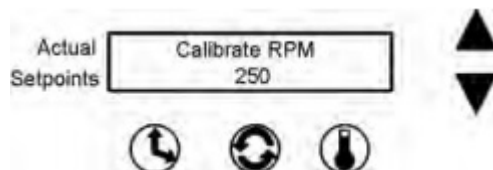


9.1.2. From the screen below, press the down arrow twice to bring up the following screen.



9.1.3. Press the Speed button beneath RPM.

9.1.4. The value shown on this screen is the present speed set-point. Using the up and down arrows, increase or decrease the platform speed until the reading on an independent, accurate speed measuring device matches the shaker speed set-point.

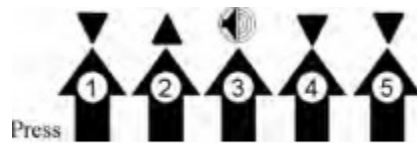


9.1.5. When finished, press the Speed button to save the setting. The display will return to the Calibrate - RPM Temp screen. Or, if nothing is pressed for about 15 seconds, the display will revert to the Operating Screen and the setting will be automatically saved to memory.

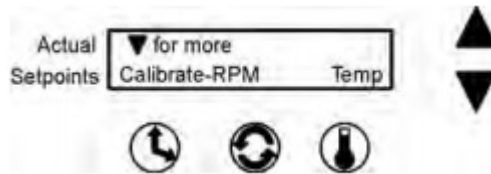
<p><b>Frederick National Laboratory for Cancer Research</b> <i>sponsored by the National Cancer Institute</i></p>	<p>HPV Serology Laboratory Standard Operating Procedure</p>	
<p>Use and Maintenance of the Forma Scientific Orbital Shaker</p>		
<p>Document ID: HSL_EQ_011</p>	<p>Version 1.0</p>	<p>Page 6 of 8</p>

9.2. Calibrate Shaker Temperature

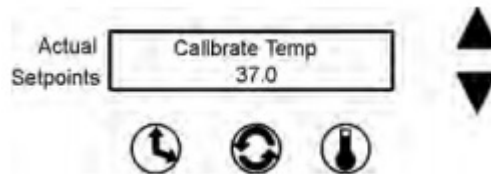
9.2.1. Access the Configuration menu by pressing the sequence shown below.



9.2.2. The screen below will appear on the display (shown below). Press the Temperature button beneath Temp.



9.2.3. Using the up and down arrows, increase or decrease the temperature value to match an independent, accurate temperature measuring device (NIST traceable thermometer) placed near the level of the platform. When selected, press the Time, Speed, or Temp button to save the setting. The display will return to the Calibrate - RPM Temp screen. Or, if nothing is pressed for about 15 seconds, the display reverts to the Operating Screen and the setting is automatically saved to memory.



**10. MAINTENANCE**

10.1. All spills should be cleaned up immediately.

10.2. Quarterly Maintenance

10.2.1. Spray the internal unit with Cavicide and let it sit for at least 3 minutes prior to being wiped with a clean low-lint wipe.

10.2.2. Spray the internal unit with Ster-ahol and wipe with a clean low-lint wipe.

10.2.3. Spray the window and door with Cavicide and let it sit for at least 3 minutes prior to being wiped with a clean low-lint wipe.

<p><b>Frederick National Laboratory for Cancer Research</b> <i>sponsored by the National Cancer Institute</i></p>	<p>HPV Serology Laboratory Standard Operating Procedure</p>	
<p>Use and Maintenance of the Forma Scientific Orbital Shaker</p>		
<p>Document ID: HSL_EQ_011</p>	<p>Version 1.0</p>	<p>Page 7 of 8</p>

10.2.4. Spray the window and door with Ster-ahol and wipe with a clean low-lint wipe.

10.2.5. Document maintenance performed on HSL\_EQ\_011.01: Orbital Shaker Use and Maintenance Form.

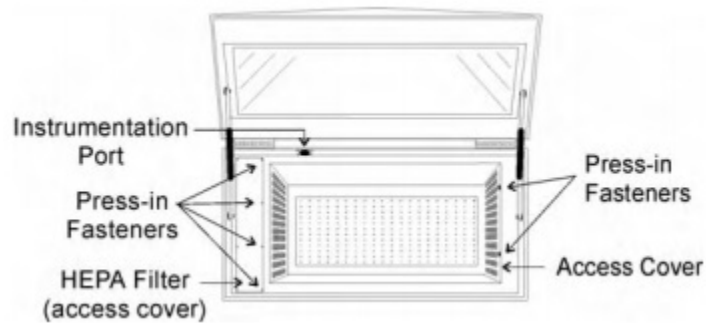
10.3. Annual Calibration

10.3.1. Facilities, Maintenance and Engineering (FME) or a contracted vendor shall certify and perform annual preventive and calibration maintenance of Orbital Shaker.

10.4. Biennial Maintenance

10.4.1. Check and change the HEPA filter every two years.

10.4.1.1. Changing the HEPA filter:



10.5. Document all maintenance performed on HSL\_EQ\_011.01: Orbital Shaker Use and Maintenance Form.

**11. ATTACHMENTS**

11.1. Not applicable

<p><b>Frederick National Laboratory for Cancer Research</b> <i>sponsored by the National Cancer Institute</i></p>	<p>HPV Serology Laboratory Standard Operating Procedure</p>	
<p>Use and Maintenance of the Forma Scientific Orbital Shaker</p>		
<p>Document ID: HSL_EQ_011</p>	<p>Version 1.0</p>	<p>Page 8 of 8</p>

**12. REVISION HISTORY**

Date Changed	Version #	Changes	Reasons
13Mar17	New	Create new SOP for the use and maintenance of the Forma Scientific orbital shaker	Currently no SOP



Orbital Shaker Use and Maintenance Form

**Form ID: HSL\_EQ\_011.01**  
Associated SOP: HSL\_EQ\_011

Version 1.0

Page 1 of 1

Equipment ID:

Calibration  
Date:

Calibration  
Due Date:

Date	Analyst	Speed Used (RPM)	Temp (°C)		Activity Performed/ Comments
		<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Cavicide, Lot #: _____ <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #: _____ <input type="checkbox"/> N/A	<input type="checkbox"/> N/A
		<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Cavicide, Lot #: _____ <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #: _____ <input type="checkbox"/> N/A	<input type="checkbox"/> N/A
		<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Cavicide, Lot #: _____ <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #: _____ <input type="checkbox"/> N/A	<input type="checkbox"/> N/A
		<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Cavicide, Lot #: _____ <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #: _____ <input type="checkbox"/> N/A	<input type="checkbox"/> N/A
		<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Cavicide, Lot #: _____ <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #: _____ <input type="checkbox"/> N/A	<input type="checkbox"/> N/A
		<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Cavicide, Lot #: _____ <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #: _____ <input type="checkbox"/> N/A	<input type="checkbox"/> N/A
		<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Cavicide, Lot #: _____ <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #: _____ <input type="checkbox"/> N/A	<input type="checkbox"/> N/A
		<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Cavicide, Lot #: _____ <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #: _____ <input type="checkbox"/> N/A	<input type="checkbox"/> N/A
		<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Cavicide, Lot #: _____ <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #: _____ <input type="checkbox"/> N/A	<input type="checkbox"/> N/A

Review By/Date:

QA Review By/ Date: