



UNIVERSITY OF
LEICESTER

**University of Leicester Research Governance Office
Standard Operating Procedures**

SOP HTA-A1016B UoL

Haier Temperature Monitoring Testing

Version 1.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

1.0 Introduction

Where samples are kept frozen, or refrigerated or at ambient temperature, the monitoring system in place must be periodically stress tested to ensure the monitoring system is functioning properly.

This testing is good practice to ensure that we are remaining compliant with the Human Tissue Authorities Research standards for Premises, Facilities and Equipment (PFE2c).

2.0 Scope

The purposes of this SOP are to outline how to undertake the stress test to ensure the system is functioning correctly and reporting accurately. This will ensure any issues are identified early, to prevent

The purpose of this SOP is to ensure that all UoL staff, students and external collaborators understand the requirements of the Human Tissue Act (HT Act) regarding the procedure for monitoring the temperature where HTA licenced samples are required to be stored.

Definitions:

DI	Designated Individual
HTA	Human Tissue Authority
HT Act	Human Tissue Act
PFE	Premises, Facilities and Equipment
PI	Principal Investigator
RGO	Research Governance Office
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

The method of testing is as follows:

For a low temperature device, the simplest method is to remove the end of the probe attached to the sensor unit from the space it is monitoring and allow ambient temperature to raise the probe to the set threshold and trigger an alarm.

Where possible the probe should be removed from the unit cavity and the door shut until the probe is returned to its normal position. If this is not possible then the threshold on the monitoring system can be lowered to a point that the probe triggers an alarm and the system responds.

Unless as part of a scheduled defrosting of the unit, it is not acceptable to have the door to a freezer or other unit left open for the duration of the test as this will cause more load on the storage unit and allow warm air into the cavity, potentially endangering the contents and/or causing excess buildup of ice around the doorway. Please ensure freezer defrosting is documented as per HTA_A1009-UoL, appendix 3

If carried out during the defrosting process, once the initial alarm is acknowledged, the individual probe for that unit should be suppressed via the website for the remainder of the process to avoid any further unnecessary alarms being raised. Once completed and the unit returned to duty, the probe must be reinstated once operating temperature has been achieved.

Where required, ambient/room temperature probes are to be tested in the latter manner, by adjusting the alarm thresholds.

In all scenarios, it is imperative that the placement or settings for the probe are returned to normal following the test.

3.1 Testing alerts to UoL Security Services

To test the system through to the ultimate end, retaining the probe outside of its monitored unit or threshold for a time beyond that set in the system will trigger an alarm to the Security Services' Control Room and a text to speech message will be made to alert the duty operative to the alarm condition.

The Security personnel responding will then contact a designated member of the group responsible for the unit or area in alarm, as arranged and specified in the Haier protocol, to alert them as to the unit in alarm, its location and the nature of the problem. The person receiving must acknowledge the call and note the details, then alert the person/s with responsibility for the individual unit to respond and take appropriate action.

3.2 Reporting and recording

All persons involved in testing within Departments must to have access to the relevant area of the Realtime-online system website (<https://www.realtime-online.com/>) and make an assessment of response, based upon the information given and data from the online system.

Records of each test will be logged as part of the acknowledgement process within the online system.

If requested from RGO, a report can be made from this information using the website or testing documented using form HTA-A1009-UoL, Appendix 5.

3.3 Frequency of Testing

The testing is to be made quarterly for local alerts and response, with an annual test to cascade to Security Services. Emphasis on testing around the University extended closure periods should be considered a priority i.e., Easter Break and Christmas breaks. PDs will remind PIs of the stress testing around periods of extended university closure.

As with all alarm notifications the test should be noted as such in acknowledging the alarm on the system website, using the drop-down menu, adding any relevant comment as required.

This is to be done within the time for escalation unless the full cascade to Security is being carried out.


4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigators (CI) / Principal Investigators (PIs)	Chief Investigators (CI) / Principal Investigators	Stress testing of the system supported by PDs. Reporting and recording of the testing as per HTA-A1016A-UoL and HTA-A1009-UoL.

Responsibility	Undertaken by	Activity
	(PIs) / Delegated Staff	
Person Designated (PD)	Person Designated (PD)	Email reminder to devolved staff in undertaking the stress taking for holidays.

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Tim Barnes	Person Designated (PD)	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding 	28/11/2024

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)