

**TITLE: WAREHOUSE TEMPERATURE & HUMIDITY DISTRIBUTION VERIFICATION  
PROTOCOL - SUMMER SEASON 2017**

**Protocol Number** MAP- WH-xxx-xxx-P

**Revision**

0

**Issued Date**

dd-mm-yyyy

**COMPANY NAME:**

XXXXXXXXXX

**SITE:**

WAREHOUSE-

**LOCATION:**

XXXXXXXXXX

**PROTOCOL PREPARED BY**

**NAME**

**SIGNATURE**

**DATE**

**Name:**

**Title:**

**Company:** Vacker Global

dd- mm-yyyy

**PROTOCOL APPROVED BY**

**NAME**

**SIGNATURE**

**DATE**

**Name:**

**Title:**

**Company:** Vacker Global

dd- mm-yyyy

**PROTOCOL REVIEWED & APPROVED BY**

**NAME**

**SIGNATURE**

**DATE**

**Name:**

**Title:**

**Company:**

**Name:**

**Title:**

**Company:**

**Name:**

**Title:**

**Company:**

**CHANGE HISTORY**

**NAME**

**REASON FOR CHANGE**

**REVISION**

**ISSUED DATE**

New document

0

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**SCOPE OF THIS PROTOCOL :**

<b>Study type</b>	Temperature and Humidity Mapping study
<b>Client Name</b>	XXXXXXXXX
<b>Asset Type</b>	Warehouse-
<b>Description and Location</b>	Sharjah, UAE
<b>Temperature range to be mapped</b>	Low limit 15°C High limit 25°C
<b>Humidity range to be mapped</b>	
<b>Duration of testing</b>	
<b>Date of Testing</b>	

**Reference Standards :** This mapping study is carried out as per WHO Technical Report Series,  
No. 961, 2011.

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**1. IDENTIFICATION OF THE EXECUTION TEAM**

In order to identify the persons who have participated in the execution of this temperature & humidity distribution verification, a specimen of their signature and initial is shown below, beside their name and title.

Name	Title	Signature	Initial

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**2. DEFINITIONS AND ACRONYMS**

In order to facilitate the comprehension of terms and acronyms used in this document, a brief technical definition is shown below.

Terms	Definitions
Change Parts	Parts to fit different size / format or application.
Deviation	Any discrepancy between the protocol and the actual performed test, test function methodology etc.
Instrument	A device that interprets a mechanical, digital or analog signal generated by a sensor, and converts it into engineering units (°C, % RH, mA, etc.) through scaling.
Key Operating Parameters	Parameters that must be maintained to process or produce products with consistent quality attributes and those that may have an impact on the proper operation of the equipment.
Main Equipment	Major equipment to be qualified.
D	Deviation
ID	Identification
N/Ap.	Not Applicable
N/Av.	Not Available
N/Sp.	Not Specified
NIST	National Institute of Standards and Technology
CFR	Code of Federal Regulations
PM	Preventive Maintenance
QA	Quality Assurance
QC	Quality Control
S/N	Serial number

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**3. SCOPE**

The temperature & humidity distribution verification protocol is a comprehensive document, which will be used to guide the executants, in the verification of the temperature & humidity distribution inside the warehouse for summer 2017.

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**4. OBJECTIVE**

The purpose of this Mapping Study is to:

- ❖ Temperature mapping study to analyze distribution of temperature inside the whole area.
- ❖ Humidity mapping study to analyze distribution of humidity inside the whole area.
- ❖ Briefly describe the equipment, its major components and their roles.
- ❖ Ensure that appropriate identification and documentation are in place.
- ❖ Ensure that the physical characteristics are compatible with planned equipment utilization.
- ❖ Ensure that appropriate operation procedures and training program are in place.
- ❖ Hot and Cold points of the Warehouse will be identified.
- ❖ Locations for placing sensors for continuous monitoring will be recommended based on the hot and cold points.
- ❖ This mapping study will be carried out for two seasons.ie, summer and winter. The recommendations issued in first climatic study will be reviewed and revised after the second climatic study. The results of winter will be considered as worst case scenario and the final recommendations will be considered accordingly.
- ❖ Number of data loggers are determined based on the volume of the Warehouse and as per relevant WHO Standards.

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**5. RATIONALE**

The study of the temperature & humidity distribution inside the Warehouse is the establishment of documented evidence of the temperature & humidity distribution for summer 2017.

The protocol is designed to allow analysis of temperature & humidity distribution inside the warehouse. Temperature & humidity distribution will be analyzed as follows:



**Warehouse temperature & humidity distribution verification - Summer 2017.**

**a) Temperature & humidity distribution of Warehouse under loaded condition with a load of 65-75%**

The temperature & humidity distribution verification must be conducted by trained and experienced technical personnel and must be documented in a scientific manner using this established format.

The study is meant to be representative and to be close to the real use of the warehouse. The temperature & humidity distribution study is to be executed during normal working condition

IMINI Temperature & humidity Data Loggers will be used to measure and record temperature & humidity. Each data logger has been calibrated and calibration certificates included in the reports will be placed in the Supporting Documents section.

CONSOLE PLUS SOFTWARE will be used to program data loggers, to download data and to generate reports which are compliant to PIC/S GMP Annex 11 and 21 CFR Part 11 requirements.

The temperature & humidity distribution verification documented in this protocol only covers Warehouse of Xxxxxxxx located in UAE



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**6. APPLICABILITY**

All Vacker Global personnel, when performing the Temperature & humidity Distribution Verification, shall follow this Temperature & humidity Distribution Verification protocol.

**7. RESPONSIBILITY**

This Warehouse temperature & humidity distribution verification protocol must be respected by all Vacker Global and XXXXXXXX employees during processing.

The responsibility of the Warehouse temperature & humidity distribution verification is attributed to the following:

Responsibilities		
Task	Vacker Global	XXXXXXX
Make available all technical documentation required for the mapping of the warehouse.		✓
Collect information.	✓	
Write the protocol.	✓	
Review and approve the protocol.	✓	✓
Coordinate activity.	✓	✓
Arrange loading and unloading goods for the test		✓
Execute the test described in the protocol.	✓	
Compile and analyze data.	✓	
Issue the final report.	✓	
Review and approve the final report.	✓	✓

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## 8. DOCUMENTATION

### 8.1 MANUAL ENTRIES IN PROTOCOL

- ⊕ All manual entries will be written in indelible ink.
- ⊕ Any error must be crossed out with a single line stroke, and the correct information must be entered below or above the error.
- ⊕ All corrections must be initialled and dated.

### 8.2 DATA SHEETS

Information will be directly recorded in the Section «Test Data Sheet» of this protocol. Here is a brief description of each section:

Section	Description
Data	Schema, tables, raw data, summary tables.
Comments	Discussion of any unusual observations during the test or significant test conditions not defined in the test procedure.
Tested by	Signature and corresponding date for the person performing the test.
Verified by	Signature and corresponding date for the person verifying the test data.

## 9. TEMPERATURE & HUMIDITY DISTRIBUTION VERIFICATION REPORT

The temperature & humidity distribution verification report will be written following the execution of the protocol and will include the sections listed below.

Section	Description
Objective	Description of the objectives of the Warehouse temperature & humidity distribution verification.
Summary	Summary and discussion of the results of the execution of this protocol.
Conclusion	General conclusion of the temperature & humidity distribution verification inside the warehouse.

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**10. WAREHOUSE DESCRIPTION**

The Warehouse-of XXXXXXXX is located at XXXXXX

The Warehouse is designed to keep the products at a temperature between 15°C and 25°C and humidity is Less than or equal to ( $\leq 65\%$ ).

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***Please contact us for a free consultation: [sales@vackerglobal.com](mailto:sales@vackerglobal.com)***