

TITLE:

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|------------------------|-----------------|---|--------------------|------------|
| Protocol Number | Revision | 0 | Issued Date | 07-05-2018 |
|------------------------|-----------------|---|--------------------|------------|

PROTOCOL #

TITLE:

| | |
|----------------------|--------------------------------|
| COMPANY NAME: | |
| ASSET | Software for Monitoring System |
| LOCATION: | |

| PROTOCOL PREPARED BY | | |
|---|-----------|------|
| NAME | SIGNATURE | DATE |
| Name: Title: Engineer Company: Vacker LLC, Dubai | | |

| PROTOCOL APPROVED BY | | |
|---|-----------|------|
| NAME | SIGNATURE | DATE |
| Name: Title: Company: Vacker LLC, Dubai | | |

| PROTOCOL APPROVAL | | |
|--|-----------|------|
| NAME | SIGNATURE | DATE |
| Name: Title: Company: | | |
| Name: Title: Company: | | |
| Name: Title: Company: | | |

| CHANGE HISTORY | | | |
|----------------|-------------------|----------|--------------------------|
| NAME | REASON FOR CHANGE | REVISION | ISSUED DATE (dd-mm-yyyy) |
| | New document | 0 | 07-05-2018 |

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File:



www.vackerglobal.com

sales.en@vackerglobal.com

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SCOPE OF THIS PROTOCOL :

| | |
|---------------------------------|--|
| Study type | Validation of software for Temperature & Humidity monitoring system supplied by |
| Client name | |
| Asset Type | Software |
| Description and Location | Monitoring system installed at the following locations: 1. Cold rooms at 2. Warehouse at 3. Cold rooms at 4. Warehouse at 5. Cold room at |
| Date of testing | 15 May 2018 |

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- 14. STANDARD OPERATING PROCEDURES VERIFICATION **Error! Bookmark not defined.**
- 15. OPERATIONAL QUALIFICATION EXECUTION VERIFICATION..... **Error! Bookmark not defined.**

1. IDENTIFICATION OF THE QUALIFICATION TEAM

In order to identify the persons who have participated in the execution of this qualification, 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 |
|--------------------------|--|
| Application software | Application software or a program that is specific to the solution of a category of application problems and that gives a computer instruction that provide the user with tools to accomplish a task. |
| Alert system | A hardware or software based instrument or connected devices which generate any kind of alerts including Email, SMS, phone call, siren etc. upon occurrence of any preprogrammed event. |
| Auxiliary Equipment | Equipment mostly used in conjunction with the equipment to be qualified but not included in the qualification package. |
| Change Parts | Parts to fit different size / format or application. |
| Cloud based storage | Any data stored in an internet based platform, which is not physically located at the customer's premises. These data will be remotely accessible irrespective of the location. |
| Component | Any major piece, part or assembly of the main equipment or sub-equipment that does not have its own power supply and could not operate as a standalone unit (valves, switches, etc.). |
| Deviation | For IQ: Any discrepancy between the installation specifications and the actual (as found) installation. For OQ: Any discrepancy between the protocol and the actual performed test, test function methodology, testing equipment, testing material etc. |
| Hardware | Hardware is a comprehensive term for all of the physical parts of a computer, as distinguished from the data it contains or operates on, and the software that provides instructions for the hardware to accomplish tasks. |
| 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. |
| Instrument, critical | An instrument for which measurements have a direct impact on the quality of the product or proper operation of the equipment. |
| Instrument, non-critical | An instrument for which measurements have no direct impact on the quality of the product or proper operation of the equipment. |
| 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. |

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| Terms | Definitions |
|---|--|
| Operating System Software | Operating System Software is responsible for controlling, integrating, and managing the individual hardware components of a computer system so that other software and the users of the system see it as a functional unit without having to be concerned with the low-level details such as transferring data from memory to disk, or rendering text onto a display. Generally, system software consists of an operating system and some fundamental utilities such as disk formatters, file managers, display managers, text editors, user authentication (login), management tools, networking and device control software. |
| Sensor | A mechanical device (pressure switch, bimetal temperature switch, etc.), a digital or analog transducer (limit switch, pressure sensor, temperature sensor, etc.) that generates an electrical or mechanical signal to an instrument or a controller in order to be interpreted. |
| Software | Software is a generic term for organized collections of computer data and instructions, often broken into two major categories: system software that provides the basic non-task-specific functions of the computer, and application software which is used by users to accomplish specific tasks. |
| Sub-equipment | Piece of equipment, part of major equipment that possesses its own power supply that could usually operate as a standalone unit (pump, conveyor etc.). |
| 21 CFR | Code of Federal Regulation, number 21 from Food and Drug Administration (FDA) |
| D | Deviation |
| ID | Identification |
| IQ | Installation Qualification |
| IOPQ | Installation / Operational / Performance Qualification |
| MAC Address | Media Access Control Address |
| N/Ap. | Not Applicable |
| N/Av. | Not Available |
| N/Sp. | Not Specified |
| NIST | National Institute of Standards and Technology |
| OQ | Operational Qualification |
| PC | Workstation |
| PQ | Performance Qualification |
| PM | Preventive Maintenance |
| QA | Quality Assurance |
| QC | Quality Control |
| S/N | Serial number |
| SOP | Standard Operating Procedure |
| Location of original calibration certificates | |

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| Acceptance Criteria |
|---|
| 1. Calibration certificate is available and current |
| 2. Calibration tag is present on the equipment. |

| Comments:¹ |
|------------------------------|
| <i>N/Ap.</i> |
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