# DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR BIOMETRIC SYSTEM

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|---|---|
| **DATE OF QUALIFICATION** | |
| **SUPERSEDE PROTOCOL No.** | **NIL** |

| PHARMA DEVILS | DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR BIOMETRIC SYSTEM | PROTOCOL No.: |
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## 1.0 PROTOCOL PRE – APPROVAL:

**PREPARED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OFFICER/EXECUTIVE (QUALITY ASSURANCE) | | | |

**REVIEWED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OPERATING MANAGER (QUALITY ASSURANCE) | | | |
| HEAD (ENGINEERING) | | | |
| HEAD (QC-MICROBIOLOGY) | | | |

**APPROVED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (QUALITY ASSURANCE) | | | |

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## 2.0 OBJECTIVE:

- To prepare the Design Qualification document for Biometric System on basis of Design and Specification and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

## 3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of Biometric System to be installed at HVAC Area.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.

## 4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

| DEPARTMENTS | RESPONSIBILITIES |
|---|---|
| **Quality Assurance** | • Preparation, Review and Compilation of the Design Qualification Protocol cum Report.<br>• Assist in the verification of Critical Process Parameters as per the Specification.<br>• Review of Qualification Protocol cum Report after Execution.<br>• Co-ordination with Production and Engineering to carryout Design Qualification.<br>• Monitoring of Design Qualification Activity. |
| **Production** | • Review of the Design Qualification Protocol cum Report.<br>• Assist in the verification of Critical Process Parameters as per the Specification.<br>• Review of Qualification Protocol cum Report after Execution. |
| **Engineering** | • Review of the Design Qualification Protocol cum Report.<br>• To co-ordinate and support the Activity.<br>• To assist in Verification of Critical Process Parameter as per the Specification i.e.<br>• Review of Design Qualification Protocol Cum Report after Execution. |

## 5.0 PROJECT REQUIREMENTS:

To confirm that safe delivery of the equipment from the supplier site. To ensure that no un-authorized or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.

## 6.0 BRIEF EQUIPMENT DESCRIPTION:

The NIYAMA HVAC BMS encompasses state-of-the-art technology with the vision of monitoring and controlling AHU parameters within the Concord environment where accurate temperature, humidity and CFM monitoring and controlling are essential.Niyama HVAC BMS supplied by Shree Aerodynamic Products having following basic components:

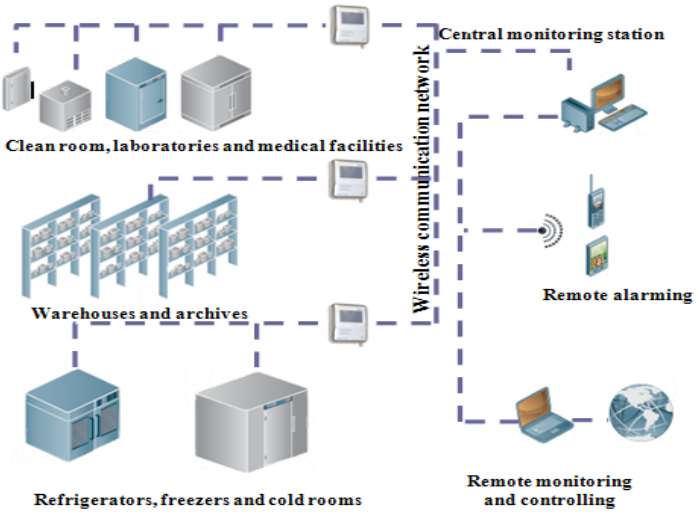
- Our modules in Ms powder Coated Control panel with necessary control outputs , supply and CFM ,Temperature ,Humidity Sensors and Real-time Display Console with Alert Indications
- Communication card for PC
- HVAC BMS software

**Distinctive Features**

- Data monitoring, logging and notification using central base receiver.
- The Internet- and web-enabled remote diagnostics and maintenance
- Controlled access to **NIYAMA HVAC BMS software** based on allocated user privileges.
- Display current temperature ,humidity ,CFM Initiates alarm as per defined parameter limits for each parameters
- Real time monitoring, logging and reporting.
- Best-in-class data analysis tools, including ability to graph and report in standard and user-defined formats.
- Wired module connections to the central computer system.
- Modules are scalable and easy to integrate for fast time-to-market applications.

## 6.1 OPERATION OF NIYAMA

- The NIYAMA HVAC BMS consist NIYAMA module, based on receiver and centralized main computer with NIYAMA-HVAC BMS software.
- Each individual NIYAMA module is fully expandable to meet custom requirement of monitoring and controlling based on different AHUs application and specifications.
- NIYAMA modules (nodes) can be connected in multiples with wire to a central monitoring, logging and configuration system operating on a server, NIYAMA facility monitoring system combines efficient monitoring and controlling with effective alarming, simplified reporting and secure data records & storage.




## 6.2 NIYAMA -HVAC BMS SOFTWARE

- NIYAMA Series is the online Monitoring system with NIYAMA-HVAC BMS software support which uses the very latest technology to fully automate temperature, Relative Humidity and Pressure monitoring and recording 24/7 providing effective control over different parameters.
- SHREE AERODYANMIC PRODUCTS has designed and developed the NIYAMA-HVAC BMS software that shows all parameter values on the PC monitor screen and keep updating and storing them in the computer as per present time intervals.
- It generates log report on bases of time, date and year that can be seen in graphs, tabular reports in PDF form. Data is stored as per pre-defined time interval. Reports are of events based likewise generated errors, modified set values of parameters, email notifications, etc. The software is easy to use and enables real time display, mimic chart, immediate visual display of data (current and historical) in graphical and printable form.
- The NIYAMA-HVAC BMS software, provided with all NIYAMA products, allows to set parameter values, take an action in correspond to out of range value of environmental parameters then generate control output as per the algorithms.
- NIYAMA-HVAC BMS software exhibit current, minimum and maximum range of all parameters and activates a settable high/low alarm for each parameter. If parameters go high or low, it gives

alarm indications.

## 7.0 EQUIPMENT SPECIFICATION:

- Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with user requirement specification.

## 8.0 CRITICAL VARIABLES TO BE MET:

### 8.1 PROCESS/PRODUCT PARAMETERS :

| Critical Variables | Acceptance Criteria | Reference |
|---|---|---|
| **Application:** Biometric System is capable to ensure that only authorized person shall access the critical area | Biometric System should meet the requirement to ensure that only authorized person access the critical area | Process Requirement |
| **Working:** Working of Biometric System | Machine identified the personnel through the finger identification and allows opening the door through the magnetic control | Process Requirement |
| Electrical Control Panel | The system should have Electrical Control Panel. | Process Requirement |

### 8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

| Critical Variables | Acceptance Criteria | Reference |
|---|---|---|
| Utility connections should be available as per the manufacturer's specification. | | |
| Power | 230 V, 1-phase, 50 Hz. Continues ups power supply | Process Requirement |
| Personal computer, For data logging & monitoring | Intel Core i5 Processor, 16 GB RAM Minimum, Ubuntu OS, 1TB Hard Drive, USB support | Process Requirement |
| Printer | Any printer. | Process Requirement |
| User | All the user list with Email ids | Process Requirement |

## 8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

| S.No. | Parameters | Acceptance criteria | Reference |
|---|---|---|---|
| 1. | Body | Powder coated panels | Design Requirement |
| 2. | Dimensions | 820 mm x 771 mm x 220.22 mm | Design Requirement |
| 3. | Weight | 50 Kg Approx. | Design Requirement |
| **Functions:** | | | |
| 4. | Temperature | -40 to +125 °C with 2 decimal point | Design Requirement |
| 5. | CFM | CFM is Based on Delta P | Design Requirement |
| 6. | Relative Humidity | 0 to 100% with 2 decimal point | Design Requirement |
| 7. | Accurate Monitoring | Locally, Centrally and Remotely. | Design Requirement |
| 8. | Display | Real Time Display ,Big LCD display | Design Requirement |
| 9. | Trends | Online and Historical | Design Requirement |
| 10. | Features | • Trends<br>• Alarm set point configuration<br>• Control parameter configuration | Design Requirement |
| 11. | Measurements | CFM, Pressure, Temperature and RH | Design Requirement |
| 12. | High and low alarm | Upper and Lower limit | Design Requirement |
| 13. | Alarm output (O*ptional*) | Dry contact or solid state | Design Requirement |
| 14. | Data printing | Individual or centralized module | Design Requirement |
| 15. | Communication | Hard wired / wireless | Design Requirement |
| 16. | Hooter | Potential free output | Design Requirement |
| 17. | User configurable | High & Low alarms setup | Design Requirement |
| 18. | Alarm output | Simple ON/OFF control | Design Requirement |
| 19. | Operator attention | Visual and Audible alarm notification | Design Requirement |
| 20. | Support | Multiple Windows | Design Requirement |

## 8.4 SAFETY:

| Critical Variables | Acceptance Criteria | Reference |
|---|---|---|
| Leveling and balancing | Biometric System should be properly balanced & leveled | Safety Requirement |
| Electrical wiring | Electrical wiring should be proper | Safety Requirement |

**8.5 VENDOR SELECTION:**

| Critical variables | Acceptance criteria | Reference |
|---|---|---|
| Selection of Vendor for supplying the Biometric System. | Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment) | Process Requirement |

**Checked By**
**Engineering**
**Sign/Date: ……**

**Verified By**
**Quality Assurance**
**Sign/Date: ……**

**Inference:**

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**Reviewed By**
**Manager QA**
**Sign/Date: ……**

**9.0 DOCUMENTS TO BE ATTACHED:**

- Any other relevant documents.

**10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):**

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## 11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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## 12.0 RECOMMENDATION:

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## 13.0 ABBREVIATIONS:

| | | |
|---|---|---|
| cGMP | : | Current Good Manufacturing Practice |
| Ltd. | : | Limited |
| DQ | : | Design Qualification |
| mm | : | Millimeter |
| Sec. | : | Second |
| RH | : | Relative Humidity |
| Temp. | : | Temperature |
| AHU | : | Air Handling Unit |
| HVAC | : | High Ventilation Air Condition |
| CFM | : | Cubic Feet Minute |
| BMS | : | Biometric System |
| PC | : | Personal Computer |
| Pvt. | : | Private |
| V | : | Volte |
| GB | : | Gega Byte |
| OS | : | Operating System |
| TB | : | Terra Byte |
| LCD | : | Liquid Crystal Display |

**14.0 REVIEWED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (ENGINEERING) | | | |

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|---|---|---|---|
| OPERATING MANAGER (QUALITY ASSURANCE) | | | |

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