



DQ, IQ, OQ, PQ FOR BIOMETRIC SYSTEM

PROTOCOL NUMBER:

DATED:

SUPERSEDES:

PROTOCOL CONTAINS TOTAL PAGES:



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1.0 DESIGN QUALIFICATION

1.1 Define the Biometric Technology Used. It's Principle and Capturing System. E. g

S.No.	Technology	Principle	Capturing Device
1.	Face Recognition	Analysis of unique shape, pattern and positioning of facial features.	Video or thermal imaging.
2.	Finger Scanning	Analysis of minutia points (ridge endings, bifurcation & branches made by ridges)	Scanning
3.	Hand Geometry	Three-dimensional image of hand using hand reader.	Hand Reader
4.	Finger Geometry	Three-dimensional image of finger.	Camera
5.	Iris Recognition	Analysis of iris i.e. colored ring of tissue surrounding pupil.	Camera.
6.	Palm	Analysis of minutia prints of palm	Scanning
7.	Retina	Retinal Imaging	Sophisticated Devices which first prompts to focus on green dot and when this is done the system flashes harmless beam of light to capture retinal characteristics
8.	Signature	The movement of the palm during signing process but not the static image of signature	Video

1.2 Define the Extraction and Comparison Process
Specify how the system will extract the captured data and convert into mathematical Code /template for comparison purpose.
Specify the threshold value for the purpose of comparison.

1.3 Define Vendor Qualifications for Biometric System.

- Number of Biometric System installed.
- Types of the technology used.
- Type of post marketing feed back received by him.

1.4 Define Final Specifications and Acceptance Criteria agreed between Vendor and User.

- Technology to be used.



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- Capturing device to be used.
- Extraction and Comparison system to be used.
- Threshold value for the match.
- Maximum Failure rate (False Rejection, False Acceptance) per day.

2.0 IQ FOR BIOMETRICS

- 2.1 Check the computer system where it will be installed.
- Check the drive.
 - Check the space required.
 - Check the ancillary softwares required on Computer.
 - Check the power supply.
 - Check the dust controls procedures used in the room where system is to be installed.
 - Check whether the system meets the agreed specifications.

3.0 OPERATIONAL QUALIFICATION

- 3.1 Define the SOP for Biometrics.
- 3.2 Check the password, which may be required to activate the system.
After activation check if the system is ready to scan, extract and compare the specified biometric feature.
- 3.3 Check for operation manual, maintenance, and calibration manuals.

4.0 PERFORMANCE QUALIFICATION

Try access to the computer system by exposing required biometric feature to the machine

Record the results as per follows

EXPT	No. of Persons taken for Trial	Failure to Activate the Screen	False Rejection	False Acceptance
1	100	-	-	-
2	100	-	-	-
3	100	-	-	-

Please Note

Specify the conditions of scanner plate during PQ (It should be free from dust and smudges).



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Specify integrity of biometric feature (The body part which is used by the system shall be intact. It shall not be cut, bruised, or damaged. For Example, if entire Finger is used, it shall not have cuts).

5.0 ACCEPTANCE CRITERIA

- Failure to activate the screen : Nil
- False Rejection : Nil
- False Acceptance : Nil

6.0 VALIDATION REPORT

- Describe the DQ, IQ, PQ, and OQ briefly.
- Describe the SOP followed for PQ
- Compare the results against the acceptance criteria.
- Conclude – System is satisfactory. System needs improvement and revalidation.

7.0 SOP'S for the Biometric System based on Finger Technology.

- Activate log on screen.
- Check the scanner plate.
- Clean it if there is smudging.
- Clean the left index finger, wipe it dry and expose the required area/ part to scanner plate.
- Wait for response.
- If allowed, proceed with you work.