



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Handling of Biometric System for Entry and Exit Procedure for Manufacturing and Filling Area

SOP No.:		Department:	Production	
		Effective Date:		
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1.0 OBJECTIVE:

To lay down a procedure for operation and handling of biometric system for Entry and Exit procedure for manufacturing and filling area.

2.0 SCOPE:

This SOP is applicable for operation and handling of biometric system for Entry and Exit procedure for manufacturing and filling areas.

3.0 RESPONSIBILITY:

Each User: use for permitting Access to specific area.
Office/ Executive QA: To enroll and delete user.
Manager/Head: Manage and Control of the System

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

DR : Door Release
Ltd : Limited
QA : Quality Assurance
SOP : Standard Operating Procedure
Pvt : Private
PD : Production

6.0 PROCEDURE:

6.1 BIOMETRIC SYSTEM:

6.1.1 It is an electronic device having the facility for fingerprint time and attendance to access/unlocking the respective door, to control the Entry/Exit of personnel as per list of authorized persons.

6.1.2 The TFT screen can display more information vividly, including fingerprint image and verification result.

6.1.3 Internal backup battery insures the device working normally when the power cut off suddenly.

6.1.4 EQUIPMENT DETAILS:

- Name : Biometric Machine
- Make : ZKTeco
- Model : K60 Pro
- Software Name : ZKFinger



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➤ Version Number : VX10.0

6.1.5 Total 12 Nos. of Biometric machines are installed.

6.1.5.1 I- Block having Biometric machines in different sections as per below details.

6.1.5.1.1 3 Piece Section Filling area- 2 machines for entry and exit.

6.1.5.1.2 3 Piece Section Manufacturing area- 2 machines for entry and exit.

6.1.5.1.3 DPI Section Filling area- 2 Machines for entry and exit.

6.1.5.1.4 Ampoule Section Filling area- 2 machines for entry and exit.

6.1.5.1.5 Ampoule Section Manufacturing area- 2 machines for entry and exit.

6.1.5.2 Q- Block having 2 Biometric machines in Filing area of ophthalmic section for entry and exit purpose.

6.1.6 MENU OPERATION:

6.1.6.1 Press the Menu key long time to open the Main Menu.

6.1.6.2 The main menu consists of:

6.1.6.2.1 User Management- Browse the user's basic information like ID, Name, fingerprint, Password and privilege and so on; Increase, edit or delete operation the basic information; set the work code for user.

6.1.6.2.2 Connection- Set up communication parameters between the equipment and the PC, including IP address, gateway, subnet mask, baud rate, device number, communication password.

6.1.6.2.3 System- Manage the data and set the system parameters, including basic parameters, interface parameters, fingerprint and attendance parameters, to maximize meet users needs in the functional display and other areas.

6.1.6.2.4 Date/ Time- Device date time should set ensure the accurate attendance time.

6.1.6.2.5 Pen drive- By USB, the user info and attendance data etc. can be imported to the accordingly software to deal or import the user information for other fingerprint devices to use.

6.1.6.2.6 Auto test- Automatically test the function of each module if it is workable, including the screen, sensor, voice, keyboard and clock tests.



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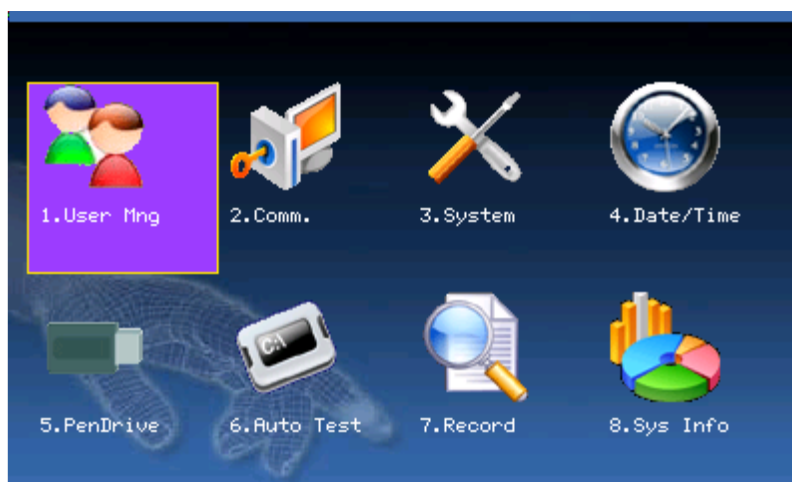
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6.1.6.2.7 Record- For query the record saved in the device convenience, query record function is provided.

6.1.6.2.8 System Info- User system information to check the current devices' saving status, its version information and so on.



6.1.7 OPERATION FOR PERSONNEL DATA ENROLLMENT IN THE BOIMETRIC SYSTEM THROUGH DEVICE:

6.1.7.1 Ensure that power supply to the device.

6.1.7.2 After Personnel Qualification for Aseptic area IPQA personnel create the login id for routine activities.

6.1.7.3 For new enrollment should be based on request and the authorized person of QA and Request can be provide by the concerned/ user as per **Annexure-II** Titled as Authorization/ Un-authorization for access in Controlled Area.

6.1.7.4 QA person shall press the M/OK key of keyboard and place the thumb/ other finger on the scanner.

6.1.7.5 Admin level finger impression will appear on the screen of the machine.

6.1.7.6 QA person shall select the user management option by pressing the key of **M/OK**.

6.1.7.7 Select the new user option and below screen will display



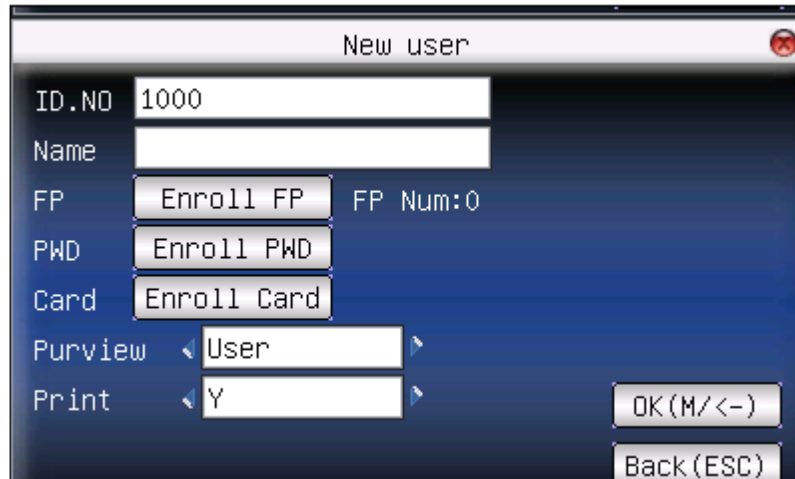
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6.1.7.8 QA person fill the ID Number and name of the new person for enrollment.

6.1.7.9 After entering the name press the ▼ key then Enroll FP icon will appear red and Enroll FP screen will open as per below



6.1.7.10 New person will place his finger/thumb on the scanner three times in the proper way.

6.1.7.11 If fingerprints are enrolled successfully, then screen will display as **Enroll success**.

6.1.7.12 After that QA person will press the ESC key and screen will show the message as **do you want to save the changes?**

6.1.7.13 Press OK key and further ESC key to back the main menu.

6.1.7.14 New person will place the finger/thumb on the scanner and his name and ID no. will show on the screen.



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6.1.7.15 ENROLLMENT NUMBERING SYSTEM

6.1.7.15.1 Authorized QA person allot the Number to any new authorized person.

6.1.7.15.2 Numbering is started from 1 and continues for separate person like 2, 3, 4, 5, 6.....

6.1.7.15.3 If person leave the organization then his enrollment number no. shall not be distribute to other person.

6.1.8 DELETE USER:

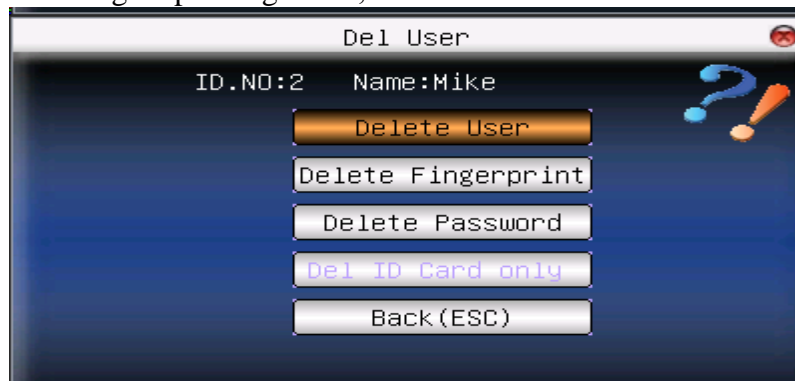
6.1.8.1 ‘Del User’ is to delete employee’s partial information or all information from the device. It is used when the following states happen

6.1.8.1.1 When employees fingerprint or password is not needed any more.

6.1.8.1.2 When employees leaves the position.

6.1.8.2 Press ▲/▼ on **Manage User** interface or use **Query User** to select the employee to be edited.

6.1.8.3 Click **Menu** to get operating menu, and then select “delete User”.



6.1.8.4 Press to confirm deletion or “esc” to abort the action and return to **Manage User** Page.

6.1.9 ENTRY & EXIT FROM CLASSIFIED AREA BY USING BIOMETRIC SYSTEM:

6.1.9.1 Always machine shall be in on condition.

6.1.9.2 Put the registered thumb/finger for impression (as per feed data) on the given screen on biometric machine.

6.1.9.3 Display will give the sign of verification. Then Open the respective door and enter into area. If unregistered person is seeking for the permission to the Biometric system then it will not



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identify the thumb/finger impression. It will ask to place the thumb/finger again and will not release the door to open.

6.1.10 PRECAUTIONS/INSTRUCTIONS :

6.1.10.1 All the entries in biometric system shall be as per authorized person list for respective area (Filling/Manufacturing).

6.1.10.2 Maintain the enrolled authorized user number list as per the format.

6.1.10.3 Each person must register biometric entry permission before entry in restricted entry area.

6.1.10.4 At a time only one person shall access the biometric device, so particular person entry can address.

6.1.10.5 Don't switch off the machine to bypass the biometric system (shall be on UPS).

6.1.10.6 If any breakdown in biometric machine, intimate to Engineering/IT or service engineer.

6.1.10.7 Entry/Exit shall be recorded in respective log sheets.

6.1.10.8 Don't access/use the system without any prior authorization/entry of data, in biometric system.

6.1.10.9 Visitors/auditors/un-authorized person's entry for restricted area is permitted along with authorized persons or Department heads only.

6.1.10.10 Filing/Manufacturing is required, shall take permission from QA, after QA approval, person can enter with qualified person only.

6.1.11 DATA BACKUP: Data is stored in server PC and can be reviewed in biometric machine.

6.1.11.1 DATA REVIEW:

6.1.11.1.1 Only Registrar and Admin level authorized person have rights to review the stored data of entry and exit time of selected person.

6.1.11.1.2 Press the thumb/finger in scanner then menu screen will display

6.1.11.1.3 Select the icon of record and press **M/OK key** then Record screen will open.

6.1.11.1.4 Enter the ID no. of selected person in ID No. then enter the details of **Start end End date**.

6.1.11.1.5 Press the key of M/OK then message will come on screen as **Loading data wait**.



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6.1.11.1.6 After few seconds data will display on screen of that person with date and time of entry and exit.

6.1.12 AUTHORIZED LEVELS: System have 3 level of control.

6.1.12.1 First Level is User level which having rights for entry and exit in respective area.

6.1.12.2 Second Level is Registrar Level which having rights for Review User Mng, Dn/Upload, Auto test, Record, Sys Info.

6.1.12.3 Third Level is Admin Level which having rights for Review User Mng, Comm., Date/ Time Dn/Upload, Auto test, Record, Sys Info, and System.

6.1.13 QUALIFICATION: Only initial qualification is required and no need of Re- Qualification.

7.0 ANEXURES:

ANNEXURES NO.	TITLE OF ANNEXURE	FORMAT NO.
Annexure – I	Access Control User Enrollment List	
Annexure – II	Request form for Authorization / Un-Authorization for Access in Controlled Areas	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production (I-Block)
- Controlled Copy No. 03 Production (Q-Block, Three Piece Section)
- Master Copy Quality Assurance

9.0 REFERENCES:

- Fingerprint Card Access control Machine Operation Manual

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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ANNEXURE – II

REQUEST FORM FOR AUTHORIZATION / UN-AUTHORIZATION FOR ACCESS IN CONTROLLED AREAS

Block: _____ **Section:** _____

Name of Employee _____

Employee Code _____

Department _____

Designation _____

Area for Authorization _____

Reason for Request _____

Prepared By
Initiating Department
(Sign & Date)

Checked By
Head of the Department
(Sign & Date)

Approved By
Manager - QA
(Sign & Date)