Manuals+ — User Manuals Simplified.

Honeywell HCiR series CFR Part 11 FDA Electronic Records & Signatures Owner's Manual

Contents

Honeywell

Honeywell HCiR series CFR Part 11 FDA Electronic Records & Signatures

Product Information

Specifications:

- **Product Line:** HCiR series
- **Compliance:** 21 CFR Part 11 FDA compliant
- **Application:** Electronic Records & Signatures

Features:

- User Management Functionalities
- Audit Trail (Tracking)
- System Data and Data Backup
- Electronic Data Record and Storage
- View of the Alarm/Event Data
- Capture and Printing

Product Line:

Resolution	Model
1024 X 768	HCiRX15-FE-FD-NC
12.1	HCiRX12-AE-FD-NC
10.4	HCiRX10-TE-FD-NC
8.4	HCiRX08-TE-FD-NC
5.6	HCiRX05-TE-FD-NC
800 X 600	HCiRW10-TE-FD-NC
640 X 480	HCiRW07-TE-FD-NC
800 X 480	HCiRW05-TE-FD-NC

Benefits:

- Compliant with 21 CFR Part 11 FDA regulations
- Cost-effective system solution for Pharmaceutical and Life Science manufacturers
- User management functionalities for enhanced security
- Audit trail for tracking system activities
- Data backup and storage capabilities
- Ability to view and save alarm/event data
- Capture and print screen functionality

Contact Information:

- For more information, please visit **process.honeywell.com**.
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Product Usage Instructions

User Management Functionalities:
The Honeywell HCiR series provides user management functionalities to ensure secure access to the system. Follow the steps below to manage users:

1. Access the system settings menu.
2. Select "User Management" option.
3. Add, edit, or delete users as needed.
4. Assign appropriate access levels and permissions to each user.
5. Save the changes and exit the settings menu.

Audit Trail (Tracking):
The HCiR series features an audit trail function to track system activities. To enable and utilize the audit trail:

1. Access the system settings menu.
2. Select "Audit Trail" option.
3. Enable the audit trail function.
4. Configure the desired level of detail for tracking.
5. Save the changes and exit the settings menu.

System Data and Data Backup:
To ensure data integrity and facilitate system recovery, the HCiR series offers system data and data backup features. Follow these steps to manage system data and perform data backup:

1. Access the system settings menu.
2. Select "System Data" option.
3. Choose the desired data backup frequency and destination.

4. Initiate a manual data backup if required.

5. Save the changes and exit the settings menu.

Electronic Data Record and Storage:
The HCiR series allows for electronic data record and storage. Follow these steps to view and manage electronic data:

1. Access the reports menu on the HMI screen.

2. Select the desired report category (Production, Alarms, Events).

3. Review the available data on the screen.

4. To save the data, insert an SD card into the designated slot.

5. Use the system interface to copy/move the data to external memory (USB).

View of the Alarm/Event Data:
The HCiR series stores detected alarm/event data in its internal memory. Follow these steps to view the alarm/event data:

1. Access the system settings menu.

2. Select "Alarm/Event Data" option.

3. Choose the desired time period or event type to view.

4. Review the displayed alarm/event data.

Capture and Printing:
The HCiR series allows you to capture and print the screen contents. To capture and print the screen:

1. Press the designated capture button on the system interface.

2. Connect a printer that supports PCL format.

3. Select the captured screen for printing.

4. Follow the printer instructions to complete the printing process.

FAQ:

- **Q: Is the HCiR series compliant with 21 CFR Part 11 FDA regulations?**

  A: Yes, the HCiR series is fully compliant with 21 CFR Part 11 FDA regulations.

- **Q: Can I save the reports on the HMI screen to external memory?**

  A: Yes, you can save the reports to an SD card and copy/move the data to external memory (USB).

- **Q: How can I print the captured screen?**

  A: You can print the captured screen by connecting a printer that supports PCL format and following the printing instructions.

Honeywell Modular system solution "Controller + HMI" is an optimized and outstanding solution for Pharmaceutical and Life Science manufacturers requiring a cost-effective system that is fully compliant with 21 CFR Part 11 FDA. Honeywell HCiR series can reach to this application programming Environment, HCiR allows the system to be validated to the 21 CFR Part11 regulations by featuring functions and features that enable.

USER MANAGEMENT FUNCTIONALITIES

- Password-protected individual unique user account.
- Password complexity
- Configure a character count for password with Flexibility
- Configurable trials to modify passwords for user accounts
- Password validity
- Multiple password level for each User Authority

AUDIT TRAIL(TRACKING):

- Non-editable Audit Trail Data Format
- The time-stamp of the modification of the parameter value and the user making the modification
- The Audit Trail records the following details:
- User creation
- User Login/Logout
- Configurable block by Administrator
- The old value and new value of the parameter change
- The time stamp of each event

SYSTEM DATA AND DATA BACKUP

HCiR offers the basic connectivity for data exchange with Honeywell solutions, Experion, ControlEdge PLC, RTU, HC900, and MasterLogic PLC by following:
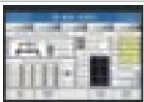
- Communication: Modbus
- Data file Transfer(FTP)
- USB, SD card

ELECTRONIC DATA RECORD AND STORAGE:
Review of the reports on the HMI Screen for Production, Alarms and event(trail). And also these data are available to save into SD card and user can copy/move the data to external memory(USB).

VIEW OF THE ALARM/EVENT DATA: Detected alarm/event data is stored in internal memory. Capture and Printing: The captured screen is available to print out on-line thru a printer to support PCL format.

PRODUCT LINE

	1024 X 768	800 X 600	640 X 480T	WIDE	800 X 480
15"	HCiRX15-FE-FD-NC			-	
12.1"	HCiRX12-AE-FD-NC	HCiRX12-TE-FD-NC		-	
10.4"		HCiRX10-TE-FD-NC		10.1"	HCiRW10-TE-FD-NC
8.4"		HCiRX08-TE-FD-NC		7"	HCiRW07-TE-FD-NC
5.6"			HCiRX05-TE-FD-NC	5"	HCiRW05-TE-FD-NC

FEATURED

- **COMPLIANT**

  Solutions to facilitate validation and reduce compliance costs with system self-documentation, electronic change management of control configuration, 21 CFR part 11 compliance and enforcement and verification of operating instructions.

- **FAST**

  A unique approach to project execution with LEAPTM project execution and technologies such as our Universal I/O removes risks and accelerates schedules.

- **VIRTUAL READY**

  A Virtual Engineering Platform allows for virtualization and simulation of all DCS components for cost-effective change implementation in a validated environment.

- **EXPERIENCED**

  More than decades working with the world's leading pharma businesses, with specialists who bring a lifetime's

experience in pharma.

- **SCALABLE**

  Delivering the most advanced technologies to the smallest and largest operations, with flexible solutions.

- **SECURE**

  Industry-leading cyber security, access control and protection against message flooding and denial of service to ensure system availability.

For more information process.honeywell.com

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Documents / Resources

FDA – 21 CFR PART 11 COMPLIANCE GUIDE	**Honeywell HCiR series CFR Part 11 FDA Electronic Records & Signatures** [pdf] Owner's Manual HCiR series CFR Part 11 FDA Electronic Records Signatures, HCiR series, CFR Part 11 FDA Electronic Records Signatures, FDA Electronic Records Signatures, Electronic Records Signatures, Records Signatures, Signatures

References

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- **User Manual**