



***Compliance reference to:***

Department of Health and Human Services  
Food and Drug Administration

21 CFR Part 11 - Electronic Records; Electronic Signatures  
Final Rule - Electronic Submissions; Establishment of Public Docket; Notice

- Federal Register / Vol. 62, No. 54 / Thursday, March 20, 1997 / Rules and Regulations
- Documented compliance / WinWare, Inc. / CribMaster Inventory Management System

Part 11 applies to any paper records required by statute or agency regulations and supersedes any existing paper record requirements by providing that electronic records may be used in lieu of paper records. Electronic signatures which meet the requirements of the rule will be considered to be equivalent to full handwritten signatures, initials and other general signings required by agency regulations

### Sign On New User

The Sign On New User dialog is used to log additional users into CribMaster. The initials of all logged in users are displayed on the User Tool Bar. You can make a user inactive by pressing his button on the toolbar. If so, desired CribMaster will employ at least two distinct identification components. A Personal Identification Number (PIN) can be assigned to each employee who has access to CribMaster. This PIN will be required at the time of "Sign On" and must be validated before the employee can gain access to the software. Once "Signed On" the employee will be tracked throughout the software via an event log and transaction logging.



### ATR Options

If you have checked "Allow Employee to Modify PIN Password" in the Additional Options section of the ATR Setup Configuration program, the NEW PIN button will appear at the top of the window. This will require you to enter your current PIN and then enter your new PIN twice for confirmation using the touch screen QWERTY keyboard. If it is typed twice identically, the new PIN will be set, otherwise the original pin is still valid. A displayed message will indicate whether the PIN is changed successfully.

### Employee List Options

#### Omit Employee from the List if no PIN is Assigned

If a PIN (password) has not been assigned to someone who appears on the touch-screen's employee list, anyone could select that employee's name and issue inventory. For tighter control, make sure that all employees have passwords. In some installations, due to the large number of employees, management has elected to avoid the administrative effort of assigning passwords. Employees without passwords can be removed from the touch-screen's employee list by checking the box labeled "Omit Employee from the List if no PIN is assigned". When this option is selected, the numeric keypad on the touch-screen is disabled. The only way an employee can be specified is by scanning a barcode badge. The reasoning is that possession of the badge is proof of identity and a password is not necessary.

#### Require PIN for each Repeat Transaction

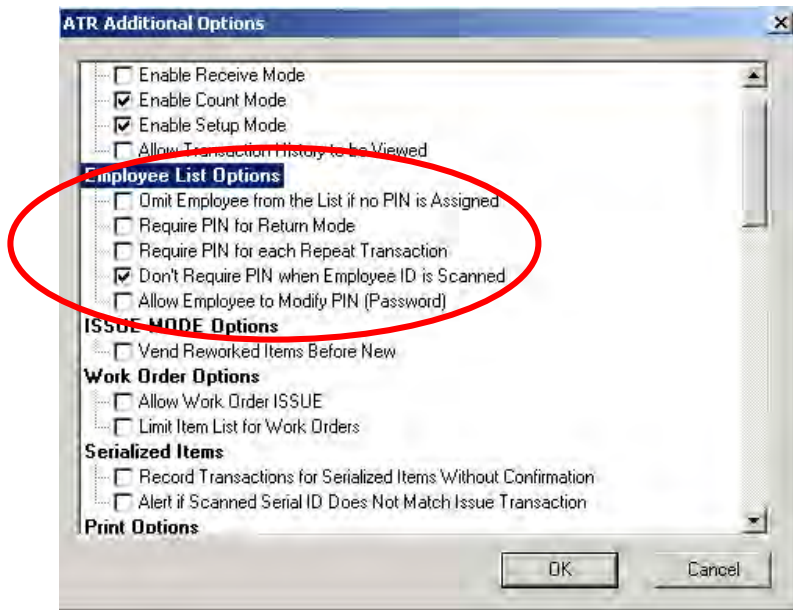
Normally after an employee has entered a PIN (password), one or more transactions can be completed. The PIN does not have to be entered for every transaction just once at the beginning. Before the employee leaves the touch-screen, the RESET button should be pressed to clear away the employee's name and PIN. If the employee forgets to press the RESET button, the

system will reset automatically after about 45 seconds. But before the 45 seconds elapse, a second employee could approach the touch-screen and issue inventory in the name of the first employee. If this is a concern, you can require that the PIN be entered for every transaction during a visit to the touch-screen, not just once at the beginning by checking the box labeled "Require PIN for each Repeat Transaction".

### Don't Require PIN when Employee ID is Scanned

Some ATR users feel that if an employee has scanned an ID badge it is unnecessary to also require a PIN. If you check the box labeled "Don't Require PIN when Employee ID is Scanned" the PIN will not be required when the ID is scanned.

### Allow Employee To Modify PIN (Password)



To operate effectively, the agency must function on the same technological plane as the industries it regulates. Just as firms realize efficiencies and benefits in the use of electronic records, FDA should be able to conduct audits efficiently and thoroughly using the same technology. For example, where firms perform computerized trend analyses of electronic records to improve their processes, FDA should be able to use computerized methods to audit electronic records (on site and off, as necessary) to detect trends, inconsistencies, and potential problems.

### Email report formats

CribMaster uses Crystal Reports to produce all of its reports. When Emailing reports, CribMaster exports the report do a disk file that is then attached to an email that is sent to the address you specify. You may specify the format of the file produced for the email by preceding the email address with the proper specification. Acceptable formats are listed below with a sample report address to support@wwga.com.

CMR: Crystal Report format    CMR: support@wwga.com  
RPT: Crystal Report format    RPT: support@wwga.com  
HTM: Html format            HTM: support@wwga.com  
CSV: Comma Separated Values    CSV: support@wwga.com

TAB: Tab Delimited Values Tab: support@wwga.com  
XLS: Excel XLS: support@wwga.com  
RTF: Rich Text Format RTF: support@wwga.com  
DOC: Microsoft Word Doc: [support@wwga.com](mailto:support@wwga.com)

### Automatically exporting reports

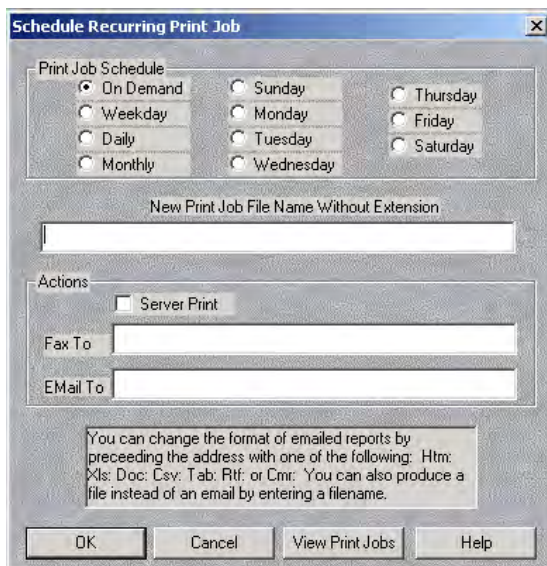
You may also have a Crystal report exported to a file by entering a file name instead of an email address. You may do this anywhere an email address is specified: Send Dialog, Schedule Dialog, or Supplier Email address. If your filename does not begin with \ or C: (Any drive letter will do), you must specify a format indicator from the above list.

### Scheduling Reports

CribMaster supports scheduling of reports to be produced automatically by CmServer daily, weekly, or monthly. To schedule a report, invoke the dialog used to produce the report, enter the parameters you wish for the report, and press the schedule button. If there is no schedule button on the dialog, the report may not be scheduled for automatic printing (POs and labels).

The schedule dialog will be displayed. Choose the time interval you want – OnDemand, Daily, Monthly, or a day of the week for weekly reports. Give the report a name that will enable you to identify it in the future. This name is used to create a file so only characters that are valid in a file name may be used. You are not allowed to edit scheduled reports (you must delete the report and schedule it again.) After you have named the report, choose the action codes you desire:

OnDemand reports do not execute automatically. To use them, you invoke the Scheduled Reports dialog from the Reports menu, choose the report, and press the Execute button.



### 11.3 Definitions

(5) Digital signature means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set up parameters such that the identity of the signer and the integrity of the data can be verified.

#### Using CribMaster one has the ability to:

Require an Employee ID, Badge, BioMetric Handscan, Proximity Badge, BioMetric Thumbprint, and associated personal identification number to gain access. Once validated, electronic signatures are documented for each transaction type.

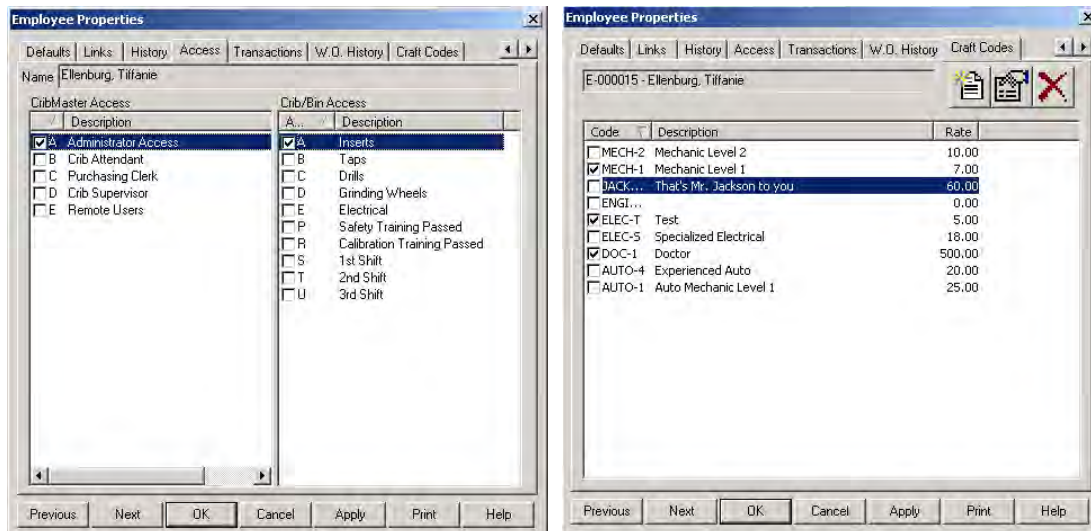
(6) Electronic records means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, distributed by a computer system.

## Subpart B

### 11.30 Controls for Open Systems

Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and as appropriate the confidentiality of the electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall included those identified in 11.10 as appropriate and additional measures such as document encryption and digital signature standards to ensure as necessary under the circumstances, record authenticity, integrity, and confidentiality.

Based upon the security profile, rights, and privileges of the user signed into the system all access can be assigned permission by functions, access level, class code and craft code. Documents can be restricted based upon the above privileges. All access must first be validated before any rights will be assigned.



### 11.50 Signature Manifestations.

(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

- (1) The printed name of the signer;
- (2) The date and time when the signature was executed; and
- (3) The meaning (such as review, approval, responsibility, authorship) associated with the signature.

(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

Tables within CribMaster store all Employee information including but not limited to First Name, Last Name, Access, and all transaction data associated with said employee.

Transactions are time and date stamped and logged by a 5-character transaction type to record all activity. Event Logs are written to a separate location to condense all transactions and verify all processes are complete.

Separate Transactions are written to identify tasks assigned to specific tool types and functions; certifications, overrides, reservations, item limits, scraps, cycle counts, purchase request, purchase approvals, one time buys, and maintenance tasks.

Transaction Types are as follows;

ADJUS Adjust  
 BNTPN Bin to Pending Rework  
 CANCL Cancel of an Issue  
 ISSUE Issue Expendable  
 ISSUE Issue Returnable  
 PNTBN Pending Rework To Bin  
 PNTRW Pending to Rework  
 RECVE Receive  
 RETN Return To Crib  
 RTOPN Return To Pending Rework  
 RTOSP Return To Supplier  
 RWRET Return From Rework  
 RWSCP Rework To Scrap  
 SCRPR Scrap From Return  
 TRIN Transfer To Another Bin  
 TRIX Transfer To Another Bin – Change Item  
 TROUT Transfer From Another Bin  
 TROX Transfer From Another Bin – Change Item  
 XTRAN Audit Trail for an adjustment

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Transactions									
Type All, Item Type All, Trans Date 12/1/1992 - 2/15/2002									
Date	Trans#	Crib-Bin Other Bin	Employee Issued To	Item	Description	Quantity	Type	Price WONo	Extension
						Serial ID			
02/27/99	05:45PM 1686	11-01-07	E-00002	100114	Filter for K&T 180 C-500 #6384	8	RECVE	8.00	64.00
02/27/99	05:45PM 1687	11-02-03	E-00002	100118	Parker Filter 10C AV 926347	9	RECVE	4.00	36.00
02/27/99	05:45PM 1688	01-R-4081	E-00002	100267	D-Hammer	1	RECVE	11.00	11.00
03/05/99	01:31PM 1690	01-R-4074	E-00002	100260	0-150lb Torque Wrench	1	TROU	5.00	5.00
03/05/99	01:48PM 1691	101-555555	E-00002	1555555-KIT		G-8007 -1	TRIN	0.00	0.00
02/15/02	01:53PM 2390	01-R-4000	E-00 E-00009	100001 Crane, Frazier	90 Deg. 3" Diam. Square Sholder Facemill MM03SS90RH	-20	CANC	4.00	-80.00
02/15/02	01:55PM 2391	01-R-4000	E-00 E-000015	100001 Ellenburg, Tiffanie	90 Deg. 3" Diam. Square Sholder Facemill MM03SS90RH	-50	CANC	4.00	-200.00
03/05/99	03:18PM 1692	01-R-4073	E-00002	100259	0-15,000 Pressure Gauge	-1	TRIN	4.00	-4.00
03/05/99	03:18PM 1693	01-R-4074	E-00002	100260	0-150lb Torque Wrench	G-9001 -1	TRIN	5.00	-5.00
03/05/99	03:20PM 1694	02-11-3-1 101-555555	E-00002	100260	0-150lb Torque Wrench	G-8007 1	TROU	5.00	5.00

11.70 Signature/Record linking

Electronic signatures and hand written signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied or otherwise transferred to falsify an electronic record by ordinary means.

Once a transaction is written to the database it cannot be destroyed. If an attempt is made to delete a transaction CribMaster writes an XTRAN transaction. This transaction forms an audit trail of the employee attempting to corrupt or edit the database.

The dialog shows the details of an ISSUE or ISSRT transaction and allows you to make adjustments to the transaction. When adjustments are recorded, the transaction is modified and a copy of the original transaction is saved with transaction code XTRAN. If you make changes on this dialog, you will be asked to confirm the action before the transactions are actually changed.

With the appropriate permissions, the quantity, cost, and cost centers associated with any past issue transaction may be \*freely\* edited.

Changes to transaction records must be explicitly confirmed prior to being saved.

No changes are made to bin quantities, item states, or summary fields (week to date, month to date, etc.) based on the changes to a transaction

Prior to saving any changes to a transaction, a \*new\* transaction is written (type "XTRAN"), which contains all the original values of the modified transaction with the following exceptions. Note that in each such exception case, the feature does not allow the original value to be modified so no data is actually lost.

The original transaction type is stored in the OLDITEM field.

The original transaction number is stored in the BATCHID field (which we use only for grouping purposes). This allows recovery of all XTRANS records for any transaction in the database. Note that the feature permits a transaction to be edited more than once. A new XTRANS record would be recorded for each edit event.

The employee ID of the employee performing the edit is saved in the EMPLOYEE field.

No.	This is the unique internal transaction number that identifies this transaction.
Trans Date	Date of the transaction
Item	Item number
Crib-Bin	Crib-Bin of the issue transaction
Quantity	Quantity for the transaction
Unit Price	The current cost that is being used for the transaction. You may enter a new cost per item in this field.
Original Cost	The cost per item currently used on this transaction.
Current Price	The current price of the item which will be used if you choose the "Use current price" check box.
Use Current Price	A quick way to update this transaction to the current prevailing price.
Total Cost	Total cost for the transaction.
Issued To Employee	The Issued to employee This is the Employee that was logged into CribMaster when the issue was processed. This employee will be replaced with the currently logged in employee in the XTRAN transaction.
User Fields	You may change the user defined fields for the transaction but the "Week to date", "Month to date", and "Year to date" totals are not changed for the old or new settings.

### 11.10 General Requirements

(a) Each electronic signature shall be unique by one individual and shall not be reused by, or reassigned to, anyone else.

Each employee within the database has a unique identifier. This identifier cannot be duplicated. If an employee is terminated or no longer exists within the database, said employee can be marked "inactive" and thus maintain all files, transactions, issues, returns, etc for record keeping and accountability. Any employee marked inactive will not be allowed access within CribMaster.

(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.

All employee files are provided by the customer.

#### 11.20 Electronic signature components and controls

(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.



Biometric identification is the automatic assessment of a unique body feature or personal action. Biometric systems are superior because they provide a nontransferable means of identifying people not just cards or badges. The HandKey uses the uniqueness of three dimensional hand geometry to control access to your valued resources. And it does it better than any other biometric system. Results of independent field tests show that the HandKey has the best overall performance and user acceptance of any biometric device.

Using CribMaster one has the ability to:

Require an Employee ID, Badge, BioMetric Handscan, Proximity Badge, BioMetric Thumbprint, and associated personal identification number to gain access. Once validated, electronic signatures are documented for each transaction type. Each log in can require a PIN if so desired to employ at least two distinct identification components.

#### 11.30 Controls for Identification codes/passwords

(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

Within CribMaster each employee is assigned a unique ID that cannot be duplicated. Each employee is free to assign their own password (alpha or numeric) thus eliminating the possibility of any duplication of the combination of the two.

(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised.

Each employee is responsible for maintain their own password. If lost or forgotten all passwords are maintained by the System Administrator. Passwords can be edited or changed by the SA or by each employee based on their privileges.

(C) Following loss management procedure to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.

Clients of CribMaster have options for any replacement tokens, cards, or other devices to ensure the proper procedures are followed. Replacement tokens, cards, etc can be re-issued within CribMaster, Numeric identifiers can be appended to employee ID's to identify the number of times this incident has taken place for accountability and temporary tokens, cards, etc can be issued until proper measures are completed.

(D) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate an urgent manner any attempts at their unauthorized use of the system security unit, and, as appropriate, to organizational management.

Safeguards such as these will follow a tier process. Said user must have rights to the unit or pc in question, rights to the network if appropriate, rights to the database and within CribMaster any user trying gain unauthorized access to the system will receive a message "the password specified is incorrect" or "please see administrator before signing on".

(E) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.

Each token, card, etc will be validated against the database before the user gains access. If problems arise with the token, card, etc processes must be set in place for replacement. See section D.