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Equipment Log Overview

1. The Equipment Log allows users to control equipment, to record activities and to connect the use of an equipment with a batch production record.
2. Features:
3. View a list of all equipment, their status and summary information on a single screen.
4. Manage the calibration and preventative maintenance (PM) of each equipment
5. Record the calibration, PM and other activities both directly and from within a batch production record (BPR).
6. Create and print equipment labels, calibration labels and PM labels.
7. Use bar code scanners to identify equipment and to open relevant screens.
8. Manage the status of equipment and to control their availability for use based on status.
9. Identify an equipment's use in a BPR and allow the system to automatically update the Equipment Activity Log with the corresponding activity with date/time stamp of the user.

Equipment Types screen

1. The Equipment Type is used to establish the activity that is done with each equipment.
2. The activity will appear in the Equipment Log in the "Activity" field of the equipment when the equipment is identified as being used in a BPR.

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Equipment Types

	Name	Activity
✎	Balance/Scale	Weighing
✎	Blender	Blending
✎	Coater	Coating
✎	Container	Holding
✎	Heater	Heating
✎	Labeler	Labeling
✎	Measuring Device	Measuring
✎	Mixer	Mixing
✎	Press	Pressing
✎	Printer	Printing
✎	Reactor	Reaction
✎	Sealer	Sealing
✎	Timer	Timing

Equipment summary screen under Setup

Equipment

	Id	Type	Equipment #	Equipment Name	Model #	Serial #	Integrated	Integrated Status
✎	1	Balance/Scale	005	Ohaus Balance	Ranger 4000	RO554789	✓	✓
✎	2	Balance/Scale	006	A&D Floor Scale	PFK988-D600	JS65888		
✎	3	Blender	ACBL001	Acme Blender	ACBL009	ACB9900		
✎	4	Blender	DC-100	KE Double Cone Blender (150 kg capacity)	KE-100	19288		
✎	5	Blender	DC-300	KE Double Cone Blender (500 kg capacity)	KE-300	19288		

1. Column Headers and functionality
    A. ID
    B. Type
    C. Equipment #
    D. Equipment Name
    E. Model #
    F. Serial #
    G. Integrated - ⊘ indicates equipment has been integrated into software
    H. Integrated Status
        1. Yellow checkmark ⊙ indicates equipment is not communicating with software
        2. Green check mark ⊙ indicates equipment is communicating with software

2. Equipment Entry / Update screen

Equipment

Equipment Type *	Balance/Scale
Equipment # *	032
Equipment Name *	Ohaus-Ranger 4000
Model #	4000
Serial #	658818624
Calibration grace period	5 (in days)
PM grace period	30 (in days)

iGMP.TEquipment

CONFIRM   CLOSE

A. Calibration grace period in days – the equipment status will automatically update to "Calibration Due" when the calibration due date is reached.
B. When the Calibration Due date plus grace period is reached, the status changes to "Need Calibration - Do Not Use".
C. PM grace period in days – the equipment status will automatically update to "PM Due" when the calibration due date.
D. When the PM Due date plus grace period is reached, the status changes to "Preventative Maintenance Due".

3. Equipment Information screen

Equipment Information

Equipment Ohaus-Ranger 4000

General

Type	Balance/Scale
Equipment #	032
Equipment Name	Ohaus-Ranger 4000
Model #	4000
Serial #	658818624
Integrated	Ohaus-Ranger 4000

HTbEquipment01   UPDATE   TEST EQUIPMENT CONNECTION   GET WEIGHT   CLOSE

A. If a scale or balance has been integrated with InstantGMP, two new buttons will appear.
1. Test Equipment Connection button when clicked sends a signal to the equipment if it has been integrated and returns a message indicating if there is a response.

> Sending data to Equipment ...

> Response: OK

2. The Get Weight button will send a request to the balance and will indicate the weight displayed on the balance if the connection is successful.

> Sending data to Equipment ...

> Response: OK:0.5180kg

Equipment Log summary screen in Main Menu

1. Column Headers and Functionality

Equipment Log

	Id	Status	Type	Equipment #	Equipment Name	Model #	Serial #	Calibration Due Date	Preventive Maintenance Due Date	Integrated	Integrated Status
🖨	1	✓	Balance/Scale	005	Mettler Toledo	PB303-S/FACT DeltaRange	RO554789	03/13/18	03/12/18	✓	✓
🖨	2	✓	Balance/Scale	006	A&D Floor Scale	PFK988-D600	JS65888	03/09/18	03/09/18		
🖨	3	✗	Blender	ACBL001	Acme Blender	ACBL009	ACB9900	//	04/30/18		
🖨	4	✗	Blender	DC-150	Double Cone Blender (150 kg capacity)	SAI-DC-2	19288	//	04/30/18		
🖨	5	✓	Blender	DC-500	Double Cone Blender (500 kg capacity)	SAI-DC-4	19288	01/17/19	04/30/18		
🖨	6	✓	Container	007	20 Gallon Pressure Canister			01/17/19	//		

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    A.   Print icon: prints Equipment Label
        1.   Equipment #
        2.   Name
        3.   Model #
        4.   Serial #
    B.   ID: System generated number
    C.   Status (Checkmarks)
        1.   Green checkmark
            a.   In Service
            b.   Clean – Ready for Use
            c.   Calibrated – Ready for Use
        2.   Yellow checkmark
            a.   Calibration Due
            b.   Preventative Maintenance Due
        3.   Red Check Mark
            a.   Do Not Use
            b.   Needs Cleaning – Do Not Use
            c.   Needs Calibration – Do Not Use
            d.   Needs PM – Do Not Use
    D. Type
    E. Equipment #
    F.   Equipment Name
    G. Model #
    H. Serial #
    I.   Calibration Due Date
    J.   Preventative Maintenance Due Date
    K. Integrated - indicates equipment has been integrated into software
    L.   Integrated Status
        1.   Yellow checkmark indicates equipment is not communicating with software
        2.   Green check mark indicates equipment is communicating with software

2. The system automatically changes the status of an equipment under certain conditions:
    A. When the Calibration Date is reached
        1.   The status will change to "Calibration Due".
        2.   When the Calibration Due date plus grace period is reached, the status changes to "Needs Calibration - Do Not Use".

User Manual

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3. During the grace period, the system sends a weekly e-mail reminder to the user who is to be notified.
4. When the system changes the status, the change is signed as a system user.
   B. When the PM Date is reached
      1. The status will change to "Preventative Maintenance Due".
      2. When the PM Due date plus grace period is reached, the status changes to "Preventative Maintenance Due"
      3. During the grace period, the system sends a weekly e-mail reminder to the user who is to be notified.
      4. When the system changes the status, the change is signed as a system user.

3. When an Equipment Status is changed, the change is recorded on the equipment log and the signature of the person making the change is shown as the performer on the equipment log.

4. General Tab on Equipment Log
   A. When the Equipment # hyperlink is selected, the General (Equipment) screen is opened. This screen shows the information on the General Tab and the other tabs that can be opened from this screen (General, Equipment Log, Documents).

Equipment Log

Equipment Double Cone Blender (500 kg capacity)

| General | Equipment Log | Documents |

Type	Blender
Equipment #	DC-500
Equipment Name	Double Cone Blender (500 kg capacity)
Model #	SAI-DC-4
Serial #	19288
Last Cleanded On	01/17/18 09:27 AM
Last Calibrated On	/ / 12:00 AM
Last PM On	01/17/18 09:27 AM
Calibration Due Date	01/17/19 Notify Paul Miller (pm01)
Preventive Maintenance Due Date	04/30/18 Notify Paul Miller (pm01)
Integrated	Not Integrated
Status	In Service ✅
Approved By:	Quenton Miles (qm01) 01/17/18 04:45 PM EST

HTbEquipmentInfo01   UPDATE   PRINT CLEAN TAG   PRINT CALIBRATION TAG   PRINT PM TAG   SEND CALIBRATION REMINDER   SEND PM REMINDER   CLOSE

   B. The General Tab shows a summary of the equipment, due dates and status.
   C. UPDATE button: Opens the Equipment Info screen
      1. Only shown to Quality Manager.

2.   Opens screen where due dates, person to notify and status can be changed.

D.   The "Print Clean Tag" button prints the following label.

```
Clean Tag


Equipment #:        DC-500
Equipment Name    Double Cone Blender (500 kg capacity)
Model #:            SAI-DC-4
Serial #:            19288



Last Cleaned on:    01/17/18
```

E.   The "Print Calibration Tag" button prints the following label.

```
Calibration Tag


Equipment #:        DC-500
Equipment Name    Double Cone Blender (500 kg capacity)
Model #:            SAI-DC-4
Serial #:            19288



Last Calibrated on:            / /
Calibration Due Date:    01/17/19
```

F.   The "Print PM Tag" button prints the following label.

```
Preventative Maintenance Tag


Equipment #:        DC-500
Equipment Name    Double Cone Blender (500 kg capacity)
Model #:            SAI-DC-4
Serial #:            19288



Last PM on:        01/17/18
PM Due Date:        04/30/18
```

G.   Send Calibration Reminder button

1.   Sends an e-mail to the indicated person to notify

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2. E-Mail has the following text: Equipment # (hyperlink to corresponding Equipment Log record), (Equipment Name) is due for calibration on (Calibration due date).

H. Send PM Reminder button
   1. Sends an e-mail to the indicated person to notify
   2. E-Mail has the following text: Equipment # (hyperlink to corresponding Equipment Log record, (Equipment Name) is due for preventative maintenance on (PM due date).

I. Integrated Equipment
   1. If the equipment is integrated, a Test Equipment Connection button will appear on the General Tab screen.

   TEST EQUIPMENT CONNECTION

   a. When clicked, the system will send a message to the integrated equipment.

   Sending data to Equipment ...

   b. If connection is successful, a message will appear.

   Response: OK

   c. If the equipment is not connected, an error message will appear.

   We didn't receive a response in time

   2. If the integrated equipment is a scale or balance, a Get Weight button will appear on the General Tab screen.

   GET WEIGHT

   a. When clicked, the system will send a message to the scale or balance to return the weight currently on its display.

   Response: OK:11.902g

5. Equipment Info Screen
   A. This screen is accessed by clicking the Update button on the General Tab. This is shown only to the Quality Manager.

Equipment Info

Equipment Type	Blender
Equipment #	DC-500
Equipment Name	Double Cone Blender (500 kg capacity)
Model #	SAI-DC-4
Serial #	19288
Last Cleanded On	01/17/18 09:27 AM
Last Calibrated On	/ / 12:00 AM
Last PM On	01/17/18 09:27 AM

Calibration Due Date 01/17/19 📅 **Notify** Select ▼

Preventive Maintenance Due Date 04/30/18 📅 **Notifiy** Paul Miller (pm01) ▼

Status In Service ▼

Select Status
In Service
Clean - Ready For Use
Calibrated - Ready For Use
Calibration Due
Preventive Maintenace Due
Do Not Use
Need Cleaning - Do Not Use
Need Calibration - Do Not Use
Need PM - Do Not Use

iGMP.EquipmentInfo   [CONFIRM] [CLOSE]

B. The following fields are Read-Only:
1. Equipment Type
2. Equipment #
3. Equipment Name
4. Model #
5. Serial #
6. Last Cleaned on (pulled from Equipment Log)
7. Last Calibrated on (pulled from Equipment Log)
8. Last PM on (pulled from Equipment Log)

C. The following fields are always editable
1. Calibration Due Date

2. [Notify calibration] user (drop down of active users)
3. Preventative Maintenance Due Date
4. [Notify PM] user (drop down of active users)
5. Status

D. The screen must be signed by a Quality Manager to update changes.

6. When the Equipment Log tab is selected, the Equipment Log opens.
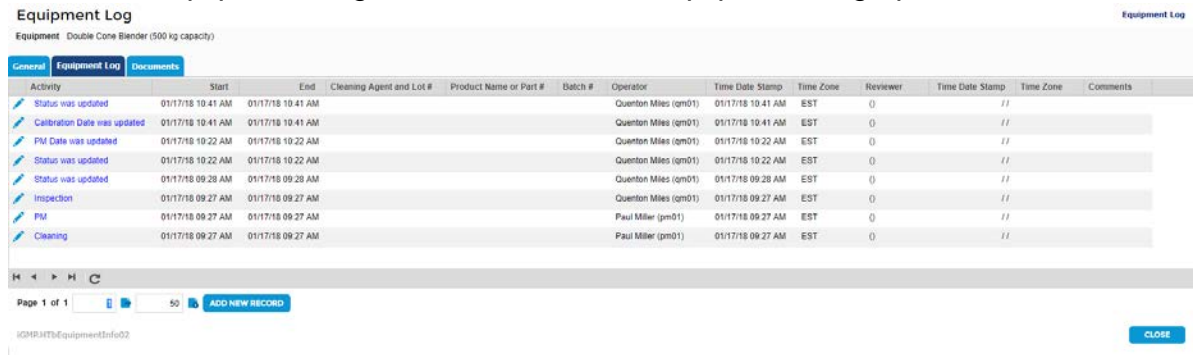
A. Clicking the edit icon or selecting the ADD NEW RECORD button opens the Equipment Log Activity screen

      B. Activity Type: drop down selection.
- 1. Cleaning
- 2. Calibration
- 3. PM
- 4. Other - When selected, another field labeled "Activity Description" appears.

      C. Performer: any user can sign
      D. Reviewer: any user can sign

7. Documents Tab
    A. This screen shows the documents associated with the selected equipment.
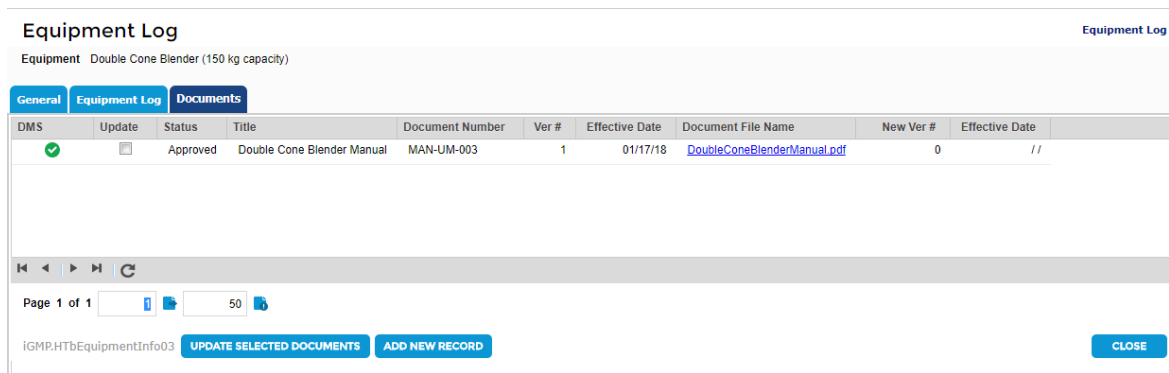
    B. Documents from the Document Management feature can be added by a Project Manager or Production Supervisor.
    C. Functions and Columns on the Documents Tab
- 1. ADD NEW RECORD: button that can only be accessed by PM, PS and QM.
- 2. Title: name of document inherited from Document Management System (DMS).
- 3. Classification: inherited from Document Management System (DMS).
- 4. Type: inherited from Document Management System (DMS).
- 5. Document Number: inherited from Document Management System (DMS).
- 6. Version: inherited from Document Management System (DMS). The version will be the most recently approved version of the document.
- 7. Document ID: inherited from Document Management System (DMS).
- 8. Effective Date: inherited from Document Management System (DMS).
- 9. Hyperlink: inherited from Document Management System (DMS). Downloads the document.

D. When the Add New Record is clicked, a Select Document screen opens. Clicking the green check mark next to a title will add that document to the Equipment.

Equipment Log Integration Configuration in Master Production Record

1. Settings in the Master Production Record can be configured so the corresponding Batch Production Record can identify equipment, interact with the Equipment Log and automatically update the use of an equipment in a batch.
2. Only the equipment selected in the Equipment Tab of the MPR will be available in the MPR manufacturing Instructions steps.

3. The MPR manufacturing instructions screen has options for identifying, using and automatically updating equipment.

MPR Instructions

Project Title	API Synthesis Example
Step	0.00
Part #	0 ⬆ Version # 0
Inventory	☐ Click if Inventory will be updated at this step
	☐ Click if equipment will be used on this step
Equipment	0 ⬆
	☐ Click if equipment activity will be updated at this step
Performer	☐ Click if Performer signature needed for this step
Verifier	☐ Click if Verifier signature needed for this step
Action	
Action	

Target 0.000000   Min 0.000000   Max 0.000000   Unit ⌄

Range

Attachment (2MB limit) [Browse...] No file selected.

Description |

iGMP.TMprManufacturingInstructions   [CONFIRM] [CLOSE]

4. When the check box labeled "Click if equipment will be used on this step" is selected:
   A. An Equipment label and selection function to select equipment from the Equipment list of the MPR will appear.

   Equipment   0 ⬆

   B. If an Equipment is selected, then the BPR manufacturing instruction will show only that equipment.
   C. A check box labeled "Click if the equipment activity will be updated at this step" has several options:

      1. If no equipment selected from the list, Equipment 0 ⬆ , then the BPR will show a drop down where the equipment can be selected from the BPR's equipment list. Either a drop down or a Scan Equipment button can be used to select the equipment on the BPR.

2. If an equipment is selected from the list, **Equipment** [0 ⬆] , then that equipment will appear in the BPR.

D. The MPR Manufacturing Instructions summary steps will show a grey checkmark.

Equipment Functions in Batch Production Records

1. The BPR manufacturing instructions shows Equipment functions if these have been set up in the MPR. Note: only equipment in the MPR Equipment Tab will be shown in the BPR manufacturing instructions.

Batch Production Record

Batch #: 0003-01-001

Cover Page	Material	Equipment	Documents	In Process Testing	Manufacturing Instructions	Executed BPR Review

Id	Status	Type	Equipment #	Equipment Name	Model #	Serial #	Calibration Due Date	Preventive Maintenance Due Date	Integrated	Integrated Status
1	✔	Balance/Scale	005	Mettler Toledo	PB303-S/FACT DeltaRange	RO554789	03/13/18	03/12/18	✔	✔
2	✔	Balance/Scale	006	A&D Floor Scale	PFK988-D600	JS65888	03/09/18	03/09/18		
4	✖	Blender	DC-150	Double Cone Blender (150 kg capacity)	SAI-DC-2	19288	//	04/30/18		
6	✔	Container	007	20 Gallon Pressure Canister			01/17/19	//		
7	✔	Container	008	10 Gallon Pressure Canister			01/17/19	01/17/19		
8	✔	Container	010	Flow Cart			12/17/19	//		

2. If the "Check if equipment will be used on this step" is not selected on the MPR and the "Click if equipment activity will be updated at this step" is not selected on the MPR, the BPR manufacturing screen will not show any equipment names or functions.

3. If the ""Check if equipment will be used on this step" is selected and the "Click if equipment activity will be updated at this step" is not selected"

A. The "Scan Equipment" button, the equipment selection drop down and the "View Equipment Log" button are shown.

SCAN EQUIPMENT

Equipment [Select Equipment ▼]
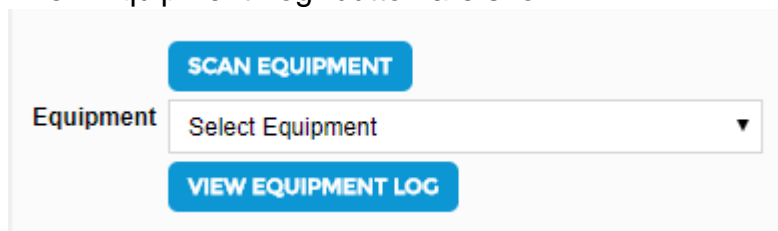
VIEW EQUIPMENT LOG

B. If the "Scan Equipment" button is used, a popup appears to scan the equipment.

Scan Equipment

Scan equipment bar code [   ]
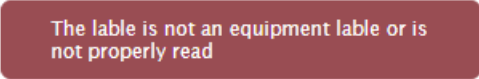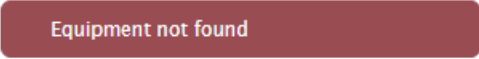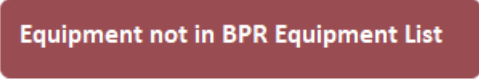
Equipment #   **Equipment Name**

HPrScanEquipmentForLogOnBpr   [CONFIRM]   [CANCEL]

C. When the bar code on the equipment is scanned:
1. The system checks to see if the bar code is from an equipment label. If not, an error message is displayed:

> The lable is not an equipment lable or is not properly read

2. The system checks to see is in the Equipment list in Setup. If not, an error message is displayed:

> Equipment not found

3. The system checks to see if the equipment in the in the Equipment tab of the BPR. If not, an error is displayed

> Equipment not in BPR Equipment List

4. If equipment has the correct label and is in the equipment list in setup and in the BRP equipment tab, the Equipment # and Equipment Name are filled in on the drop down.
D. If the scan is not used, the user selects equipment from the drop-down list.
E. If the "Click if equipment activity will be updated at this step" is selected on the MPR, the "View Equipment Log" button will appear in the BPR. When clicked, it will take the user to the "Equipment Log" popup.

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1. The Equipment Log popup will have a "Log Other Activity". When clicked, an Equipment Log activity screen will appear where the equipment activity can be recorded directly into the Equipment Log for that equipment. An Operator signature is required.

2. When confirmed, the popup closes and the corresponding equipment in the equipment log is updated.

F. If the "Click if equipment activity will be updated at this step" is selected on the MPR, the "View Equipment Log" button will appear in the BPR. When clicked, it will take the user to the "Equipment Log" popup where a "Sign to Log [activity]" button will automatically update the Equipment Log for that equipment.
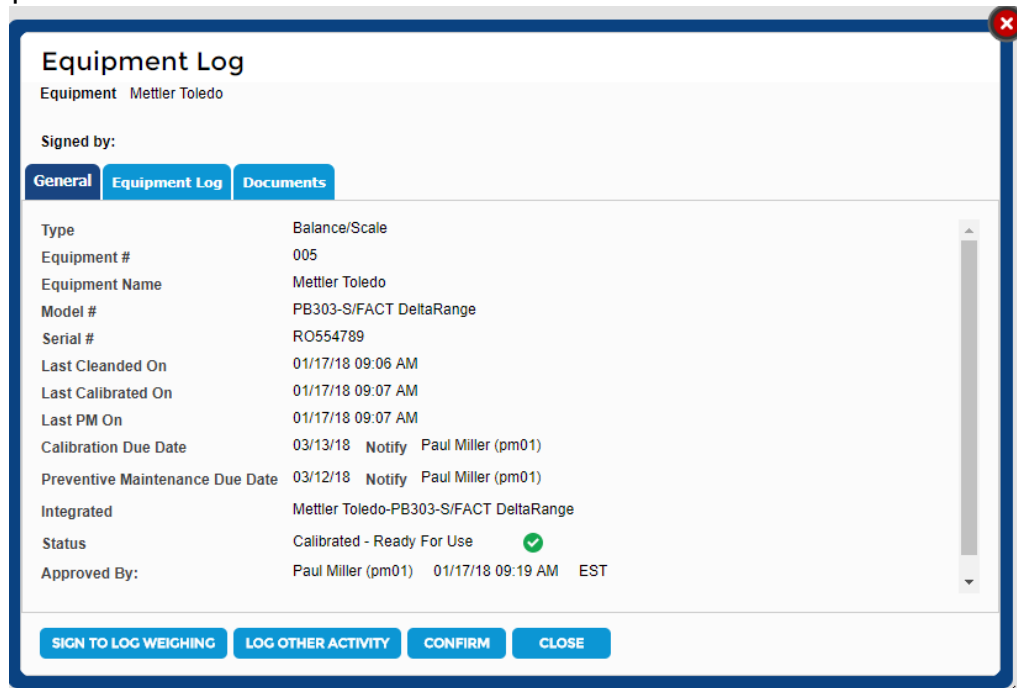
1. When the "Sign to Log [activity]" button is clicked, a signature popup appears.


2. When signed and confirmed, the popup closes and the corresponding equipment in the equipment log is updated with the following information:

a. Activity: Equipment Activity in Setup that is associated with this equipment.

b. Start Date and Time
c. End Date and Time
d. Product Name or Part #: Product name in the BPR.
e. Batch #: Batch number of the BPR.
f. Performer: Digital signature of Performer
3. When the popup is closed, the equipment name, ID and signature of Performer will appear in the BPR instruction and all other equipment selection and the Scan Equipment button are hidden.
4. If the Status includes "Do Not Use" or the checkmark is red:
   a. An "Over-Ride by Quality" button appears which only a Quality Manager who is logged in as the current user can employ.
   b. When the QM signs the Over-Ride button, the activity associated with the equipment is recorded. Use the QM signature in the Equipment Log for both activities.
5. When the Equipment Log is updated and the manufacturing step is confirmed, the equipment name in the BPR manufacturing instruction is locked and access to the equipment log is removed.
4. For each BPR manufacturing instruction summary step, the status of the equipment is shown.
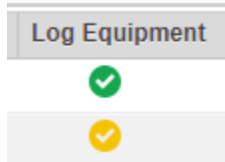
A. If the required equipment was used and automatically recorded in the log, the status shown as a green checkmark.
B. If the required equipment was not logged, the status is shown as a yellow checkmark.