	Title: **MOP 8b – Device Accountability App**

Device Accountability Application

Contents

I. PURPOSE

- The Device Accountability Application ("App") serves as a platform to replace the paper Device Accountability. Through the App, sites can:
  - Request product
  - Confirm receipt of product
  - Update disposition of products
  - View reports for all orders, packing slips, and product returns
  - Generate and print device accountability log on demand
- Devices are requested from the Sponsor when there are upcoming CONFORM cases for patients who have been randomized to receive the CLAAS device.

II. GETTING STARTED

- To access the app, you will receive an email containing a link to the inventory tracking application
  - Each individual will create a unique Personal Login
- *Notes* on your unique Personal Login
  - Use your work email to receive App email notifications
  - For security reasons, your password should be different than your other accounts and sufficiently long using a combination of characters.
  - Do not share this password with others
  - Your unique Personal Login for the App is only accessible by you.
- *Recommendation*: Though the app can be accessed via a Smartphone, it functions best in an internet browser on a computer. Any browser (Chrome, Safari, Explorer, etc.) will work.

III.   GENERAL NAVIGATION

1. Only use navigation icons <u>within</u> the app. **Do <u>NOT</u> use the back, home, undo, etc. buttons in your Internet browser.**

2. Please remember to log out when you have completed all your work. *You will be logged out automatically after 20 minutes of inactivity -- any updates that have not been saved will be lost.*

3. Any time you select a date within the application, you will need to press Ok to enter that selection.

IV.   LOGIN INSTRUCTIONS

If you are designated for access to the inventory tracking application, you will create a Personal Login for access to the functions within the program and track all activity. Please follow the steps below to create your account.

1. Access the link for the Conformal Device Accountability Application: https://apps.powerapps.com/play/9cf82348-8866-4c84-a989-02f032c8a64c?tenantId=17f64322-521f-4528-8001-aba3f775f131

    *   *Recommendation*: Bookmark this page in your browser as "CONFORM Device Accountability App" for future use.

2. Press **Start App**

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Start App

3. If this is your first time using the application, press the **Register New Account** button.
   • If you have already created an account, then skip to step 7.

Welcome, please login!

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Login to Continue!
Site Info: Main Line Health Conformal | |

Email Address: [   ]

Password: [   ]

LOGIN

REGISTER NEW ACCOUNT

4. Complete the form with your name and email, and create a personal password for your Personal Login.
   • It is recommended to use your work email
   • It is recommended to use a password that is not used anywhere else for security reasons.

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Register a New Account
Site Info: Main Line Health Conformal | |

* Full Name: [   ]

* Email Address: [   ]

* Password: [   ] Minimum 8 characters and one special character

* Repeat Password: [   ] The password values must match

REGISTER

Press **Register**

Inventory Tracking App

Register a New Account

Site Info: Main Line Health Conformal | |

* **Full Name:** Conformal

* **Email Address:** conformal@conformalmedical.com

* **Password:** ········

* **Repeat Password:** ········

REGISTER

5. **Login** to receive product and update the device accountability log.

Welcome, please login!

Login to Continue!

Site Info: Main Line Health Conformal | |

Email Address:

Password:

LOGIN

REGISTER NEW ACCOUNT

	Title:
	MOP 8b – Device Accountability App

V.   RECEIVE PRODUCT

Once logged into your account, follow these instructions to receive product.

1. This image shows the **Home Screen**
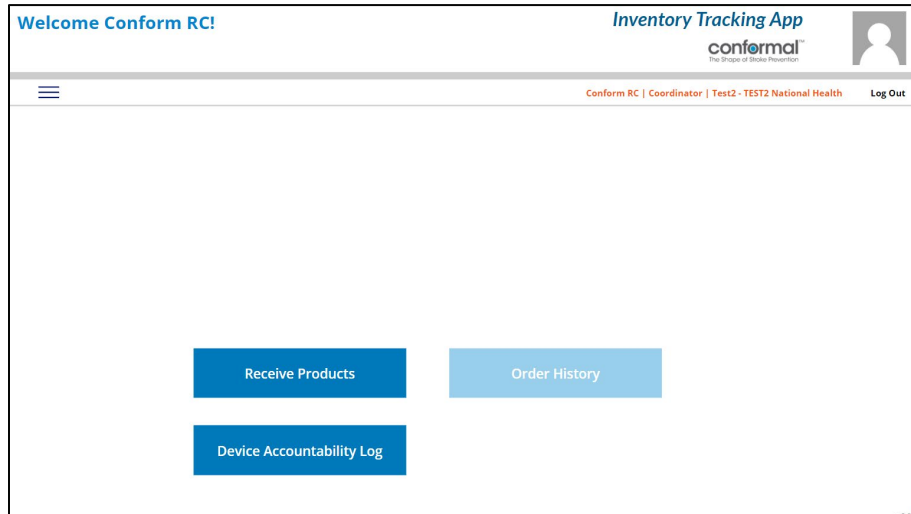
2. Click the button **Receive Products**
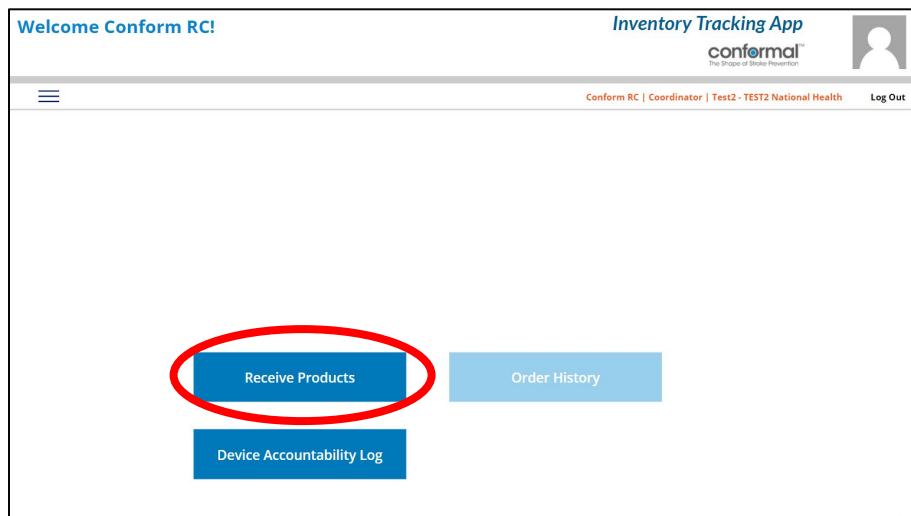
! *Note*: Do NOT acknowledge receipt of order until ALL product is received on site.

   - Left section: **Shipped Orders Panel**
   - Middle section: **Product Panel**
   - Right section: **Order Details Panel**

4. Orders that have been shipped to your site will be displayed on the left in the **Shipped Orders Panel**. The **Product Panel** and **Order Details Panel** will appear once you select your order.
   - The O-## number is the Conformal Order#
   - The tracking number and shipping date are displayed.
   - Click on the order to populate the Product Panel.

5. The **Product Panel** will populate in the middle section. The **Product Panel** contains information on the device type, lot number, and quantity
   - Confirm all product listed as shipped has been received by checking the boxes next to each line item.
   - Click the button "View Packing Slip" to view or print the packing slip for the order. Note that signatures should be completed electronically within the app. Electronic signature with the Device Accountability App is 21 CFR Part 11 compliant and can be used in place of wet signature of the paper Device Packing Slip (F-50) form upon product receipt.

6. The **Order Details Panel** will populate in the right section. The **Order Details Panel** contains the date of receipt, an option to select if any product was damaged, and the option to mark order as received.

- Confirm the correct date that product is received.
    - * Default value will always be the current date.
- Check if any product box was damaged. Default value is No.
    - * Toggle to Yes if damaged and enter details in the box below.
- **IF ALL PRODUCT** in the order has been received, then click on the **Mark Order Received** button.
- **IF PARTIAL PRODUCT** has been received (i.e., half the order has been received on site), please do not click on Mark Order Reviewed. Wait until all packages have arrived. If part of the shipment is delayed or missing, please contact your Site Manager.

7. After an order has been marked received or if there are no current orders for your site, the following message will be displayed.

Site Order Receipt

Home   Order History   David Houck | Admin | 21010 - Vanderbilt University Medical Center   Log Out

No orders available for receipt.

VI. VIEW ORDER HISTORY

1. From the **Home Screen**, Select the button **Order History** OR from the **Site Order Receipt Screen**, Select the button **Order History**
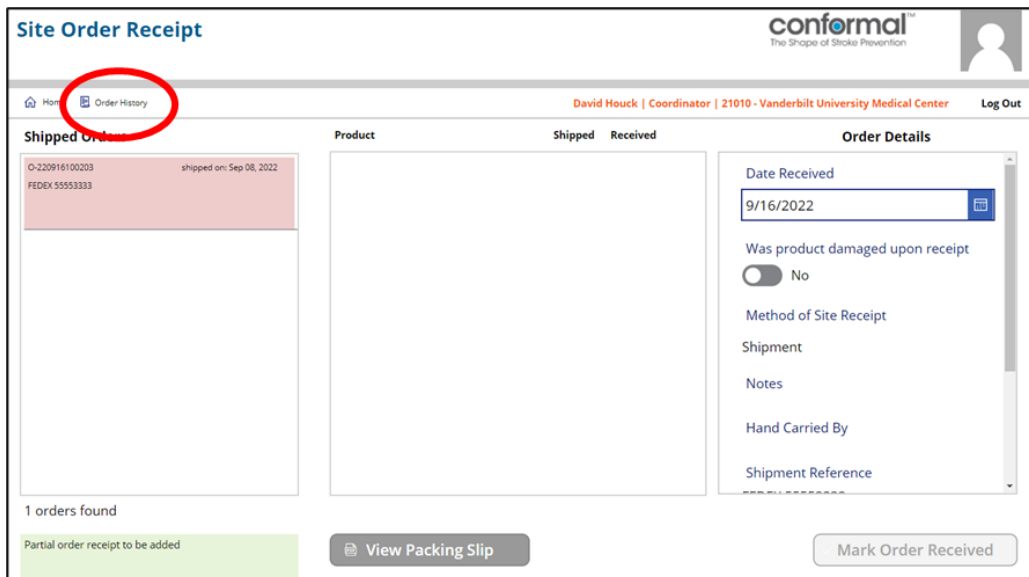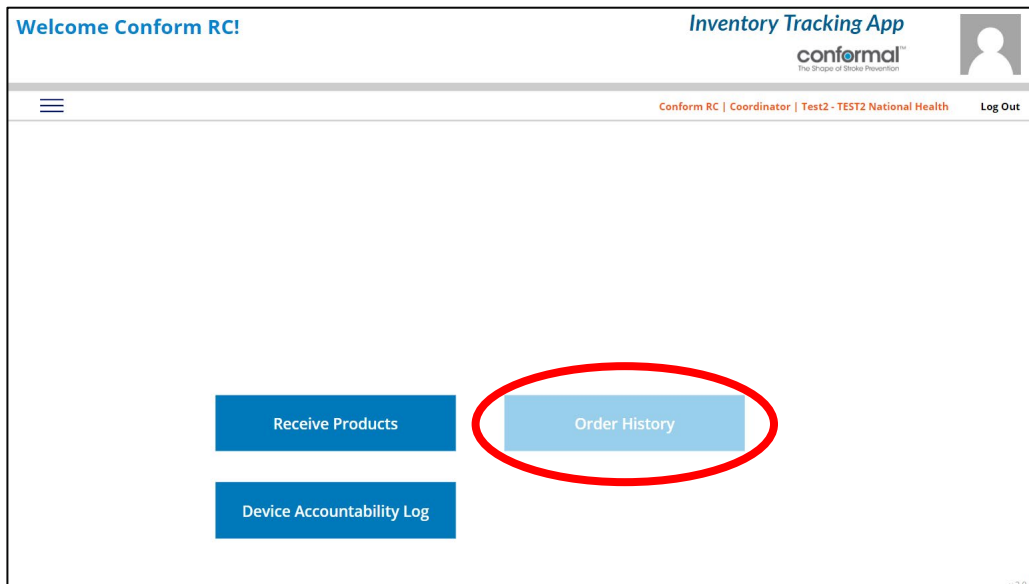
2. Review all orders that have been processed at your site.
   - Order number
   - Shipping date
   - Status
   - Date received
   - Who received the order
   - Additional comments entered at time of receipt

Site Order History   *Inventory Tracking App*
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🏠 Home   Conform RC | Coordinator | Test2 - TEST2 National Health   **Log Out**

Site Orders

O-231002102451	shipped on: Oct 02, 2023 shipped by: David Houck	Status: Received	received by: FCS User (dhouck@conformalmedical.com) received on: Sep 29, 2023	View Packing Slip
55555555				
Product damage details:				

3. View the packing slip associated with the order. You will only be able to view orders associated with your site.

Site Order History   *Inventory Tracking App*
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🏠 Home   Conform RC | Coordinator | Test2 - TEST2 National Health   **Log Out**

Site Orders

O-231002102451	shipped on: Oct 02, 2023 shipped by: David Houck	Status: Received	received by: FCS User (dhouck@conformalmedical.com) received on: Sep 29, 2023	View Packing Slip
55555555				
Product damage details:				

VII.   DEVICE ACCOUNTABILITY LOG

1. From the **Home Screen**, click **Disposition Update** to update the **Device Accountability Log (DAL)**.
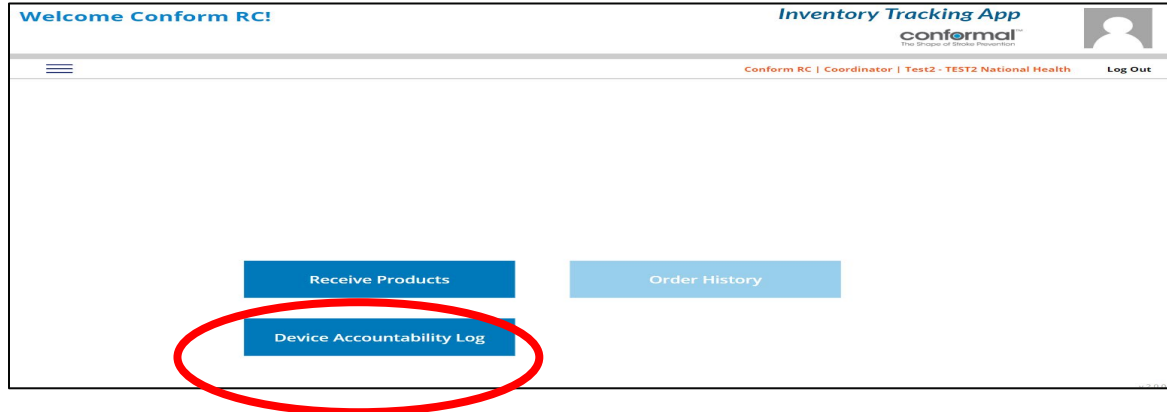
2. The **DAL** is automatically populated after you have marked an order as received. Each product received will be displayed as its own line item. The default view will show only unused product at your site. The total number is listed at the bottom.

3. Search feature:
   - Use the **Search Feature** at the top right of the screen to search by any terms used in the top line of the first three displayed columns: Product Code, Description, and Lot Number
   * The filter will automatically update as you type in the search term.
   * The number of unused items for that term will be displayed at the bottom of the table

4. Click the **Show Disposed** box to display all product that has already been given a disposition. You can limit the display to products with a disposition date in a defined window:
   a. 30 days
   b. 90 days
   c. 180 days
   d. All

5. Additional filters:
    - Additional filters can be added for type of disposition. Click on the filter icon next to the disposition column.
    - If a disposition of Returned has been selected, you will be required to enter an RGA number.
        - * Please reach out to your Site Manager for an RGA number
    - *Tip*: Use the Other box to enter a return date and tracking number for all returned product.

6. If a **Subject ID** is entered, a disposition must be selected to save the record. This error message will appear if no disposition is selected.

7. Updating Disposition
    a. A **Disposition Date** is required if any disposition is selected
    b. Any dispositions may be selected together (i.e., Used, Disposed)
        i. Exception: You cannot select both "Disposed" and "Returned"

8. Sign Off

    a. Sign off DAL updates by selecting the box at the bottom of the log.

    b. By selecting this box, you confirm you have reviewed the above information. *By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your handwritten signatures and recognize that it is prohibited to share your username and password or any other components of your signature (21CFR11.100) and are submitting this information.*

    c. The first time in a session, you will be prompted to login again with your unique user ID to acknowledge acceptance of your electronic signature.

    d. You will only be asked for the additional login once per session. Additional changes will only require you to check the box and press the **Save Changes** button.

    e. After checking the box and/or completing login, the **Save Changes** button will become active to submit the updates.

9. Monitoring
   a. A unique ID will be assigned to each inventory line in the Device Accountability Log. This number is used only for reference in the log and will not be found on package labels or packing slips.

   b. A monitoring status will be displayed for each line item in the log.

   i. Blank – No status yet

   ii. ✓ - Confirmed status

   iii. ⊘ - Monitored status

   iv. ⚠ - Open Query

   v. ⚠ - Responded to Query

   c. Queries – queries can be opened by a site monitor. You will be able to filter inventory items by open queries. Click on the query icon to access the query and respond.

You can click on the **Respond** button to enter your response. Then click save.

** Note that it may take up to 15 minutes for the query icon to be updated after a response is entered.

VIII. GENERATE REPORTS

1. To generate or print a **Device Accountability Log Report**, press the Generate Report icon in the menu bar.

2. **Device Accountability Log Reports** can be generated at any time.
   a. Reports will default to include all dates, but a date range may be specified to only report updates done in that timeframe.
   b. If the **Disposition Completed** box is <u>not</u> checked then all product, used or unused, will be included in the report.
   c. If the **Disposition Completed** box is checked, then unused product will be excluded from the report.
   d. If the **Exclude Monitored** box is checked, then product that has the "Monitored" status will be excluded from the report.
   e. All generated reports will be saved in the list and may be viewed by clicking on the **View Report** link. Reports will be organized from most recent on top to oldest.