

MOP 8b – Device Accountability App

## Device Accountability Application

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#### 1. 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 and packing slips
  - o 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.

#### П. **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.

Device Accountability Log / Dispo	sition Update	Conformal <sup>™</sup> The Shape of Stroke Prevention	2
	David Ho	uuck   Coordinator   21010 - Vanderbilt University Medical Center	Log Out
Product Code Description Lot# Site Id Order# Expy Date Subject ID	Disposition Date Deficient Used Disp	posed Returned Other	XQ

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.

Device Accountability Log Report		Conformal <sup>™</sup> The Shape of Stroke Prevention	2
🔇 Back		David Houck   Coordinator   21010 - Vanderbilt University Medical Center	Log Out

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: <u>https://apps.powerapps.com/play/9cf82348-8866-4c84-a989-</u> 02f032c8a64c?tenantId=17f64322-521f-4528-8001-aba3f775f131
  - Recommendation: Bookmark this page in your browser as "CONFORM Device Accountability App" for future use.



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2. Press Start App

Inventory Tracking App		Conformal <sup>™</sup> The Shape of Stroke Prevention
	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!		Conformal <sup>™</sup> The Shape of Stroke Prevention
	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.

Inventory Tracking App		Conformal The Shape of Stroke Prevention
	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	



MOP 8b – Device Accountability App

### Press Register

Inventory Tracking App		Conformal <sup>M</sup> The Shape of Stroke Prevention
	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!	Conformal <sup>w</sup> The Shape of Stroke Plevention
	Login to Continue! Site Info: Main Line Health Conformal
Email Address: Password:	
	LOGIN REGISTER NEW ACCOUNT



#### V. RECEIVE PRODUCT

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

1. This image shows the Home Screen

Welcome Conform RC!	Inventory Tracking App confermal busices of basis
=	Conform RC   Coordinator   Test2 - TEST2 National Health Log Out
Receive Products	Order History
Device Accountability Log	

2. Click the button Receive Products

Welcome Conform RC!	Inventory Tracking App conformal budget d back header
=	Conform RC   Coordinator   Test2 - TEST2 National Health Log Out
Receive Products Device Accountability Log	Order History

*Note*: Do NOT acknowledge receipt of order until ALL product is received on site.



- 3. You will see the Site Order Receipt Page. This page consists of three sections:
  - Left section: Shipped Orders Panel
  - Middle section: Product Panel
  - Right section: Order Details Panel

Site Order Receipt					Conformal <sup>™</sup> The Shape of Stroke Prevention
n Home 🖹 Order History		David	Houck   Co	ordinato	r   21010 - Vanderbilt University Medical Center Log Out
Shipped Orders	Product	Shipped	Received		Order Details
0-220907094627 shipped on: Sep 07, 2022 FEDEX 987654321	27mm CLAAS Implant with Delivery S 30-00214 / test1 rev A / 12/31/2024 0-220907094627			<b>V</b>	Date Received
	27mm Single Curve Access Sheath an 30-00215 / test2 rev B / 12/31/2024 0-2209070094627			<b>√</b>	9/8/2022
Shipped	27mm Single Curve Access Sheath an 30-00215 / test2 rev A / 12/31/2024			<b>v</b>	Ves Order
Orders	0-22090/094027 35mm Double Curve <b>Pars O Clus</b> 30-00271 / testő rev A 12/34/200 Clus 0-220907094627	uct		V	Product Damage Details Box was Details
					Method of Site Receipt Shipment
1 orders found	1				
Partial order receipt to be added	🗟 View Packing Slip				✓ Mark Order Received

- 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.

Site Order Receipt			Conformal <sup>™</sup> The Shape of Stoke Prevention
🏠 Home 🖹 Order History		David Houck   Coordinato	r   21010 - Vanderbilt University Medical Center Log Out
Shipped Orders	Product	Shipped Received	Order Details
0-220916100203 shipped on: Sep 08, 2022			Date Received
			9/16/2022
			Was product damaged upon receipt
			No
			Method of Site Receipt
			Shipment
			Notes
			Hand Carried By
			Shipment Reference
1 orders found			



- 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.

Site Order Receipt			Conformal™ The Shape of Strake Prevention
n Home 🗏 Order History		David Houck   Coordinator	21010 - Vanderbilt University Medical Center Log Out
Shipped Orders	Product	Shipped Received	Order Details
0-220907094627 shipped on: Sep 07, 2022 FEDEX 937654321	27mm CLAAS Implant with Delivery S 30-00214 / test1 rev A / 12/31/2024 O-220907094627 27mm Single Curve Access Sheath an 30-00215 / test2 rev B / 12/31/2024 O-220907094627 27mm Single Curve Access Sheath an 30-00215 / test2 rev A / 12/31/2024 O-220907094627 35mm Double Curve Access Sheath a 30-00217 / test5 rev A / 12/31/2024 O-220907094627	20     20     ✓       5     5     ✓       5     5     ✓       5     5     ✓	Date Received  9/8/2022  Was product damaged upon receipt  Yes  Product Damage Details  Box was opened  Method of Site Receipt  Shipment Notes
1 orders found			
Partial order receipt to be added	🖻 View Packing Slip		✓ Mark Order Received



- 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.

Site Order Receipt				Conformal <sup>™</sup> The Shape of Stroke Prevention
က Home 🖹 Order History			Houck   Coordinate	r   21010 - Vanderbilt University Medical Center Log Out
Shipped Orders	Product	Shipped	Received	Order Details
0-220907094627 shipped on: Sep 07, 2022 FEDEX 987654321	27mm CLAAS Implant with Delivery S 30-00214 / test1 rev A / 12/31/2024 O-220907094627		20	Date Received
	27mm Single Curve Access Sheath an 30-00215 / test2 rev B / 12/31/2024 0-220907094627 27mm Single Curve Access Sheath an		5 🗸	Was product damaged upon receipt
	<b>30-00215 / test2 rev A / 12/31/2024</b> O-220907094627		5 🔽	Yes
	35mm Double Curve Access Sheath a 30-00271 / test6 rev A / 12/31/2024		5 🔽	Product Damage Details
	0-220907094627			Box was opened Method of Site Receipt
				Shipment
1 orders found				INDIES
Partial order receipt to be added				✓ Mark Order Received



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		2
n Home 関 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

Welcome Conform RC!		Inventory Tracking App confermal To State Provide American	2
=		Conform RC   Coordinator   Test2 - TEST2 National Health	Log Out
De	Receive Products vice Accountability Log	Order History	.700

Site Order Rece	eipt			The Shope of Stroke Plevention
🔂 Hom 💽 Order History			David Houck   Coordinate	or   21010 - Vanderbilt University Medical Center Log Out
Shipped Order		Product	Shipped Received	Order Details
0-22919100203 FEDEX:5553333	shipped on: Sep 08, 2022			Date Received 9/16/2022 Was product damaged upon receipt No Method of Site Receipt Shipment Notes Hand Carried By Shipment Reference
1 orders found				
Partial order receipt to be add	led	🗟 View Packing Slip		Mark Order Received



- 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 H	listory	Inventory Tracking App conformal The Brape of Stoke Prevention
₩ 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 by: FC5 User (dhouck@conformalmedical.com) View Packing Slip received on: Sep 29, 2023
5555555		
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 H	listory	Inventory Tracking App confermal The Strape of Strate Preventor
🟠 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 by: FCS User (dhouck@conformalmedical.com) View Packing Slip
55555555		
Product damage details:		



#### The Shape of Stroke Prevention

#### VII. DEVICE ACCOUNTABILITY LOG

# 1. From the Home Screen, click Disposition Update to update the Device Accountability Log (DAL).

Welcome Conform RC!	Inventory Tracking App	
	тте и враг от анове Рементнот	
	Conform RC   Coordinator   Test2 - TEST2 National Health	Log Out
Receive Products	Order History	
Device Accountability Log		
		w 2.0.0r

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 <u>only unused</u> product at your site. The total number is listed at the bottom.

Devi Study Conform	<b>ce Account</b> n Pivotal	abilit	y Log /	Disposit	ion Updato	e /			Inventory Tracking App conformal <sup>®</sup> The Shape of Strale Preventor					2
슈 Home	○ Refresh Inventory	Generate Rep	port 🗌 Show	Queries 🗌 Sho	w Disposed				Conform RC	Coordinator	ordinator   Test2 - TEST2 National Health			
Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA Tr	ansferred	Other	Search	XQ
#2872 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-230809184819		TST-101 5/15/2023		12/71/2001									A
#2873 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-230809184819	~	TST-101 5/15/2023		12/31/2001									
#2874 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-230809184819	~	TST-101 5/15/2023		12/31/2001									
#3281 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-231002102451		TST-10 5/11/2024		12/31/2001									
#3282 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-231002102451	/	TST-101 5/15/2024		12/31/2001									
#3221 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-230912173804		TST-101 5/15/2024		12/31/2001									
#3222 TEST2	TESTPRODUCT TESTPRODUCT - Used for development 0-230-2173804		TST-101 5/ last modif	ied by (dhouck@	conformalmedical.com)									
#3223 TEST2	TESTPRODUCT - CESTPRODUCT - Used for development		TST-101 5/15/2024		12/31/2001									•
37 items Site Numl	per / Name								By selecting this have reviewed th By electronically accept that your the legally bindir	box, you confirm yo e above informatic signing here, you electronic signatur ig equivalent of you	ou ≜ in. eis ir ♥		Save Char	ıges



- 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

Study Conform	ce Accounta	ability	y Log /	Disposit	ion Update				Inv	entor	ry Tracki CON The Shope of	ing App formal <sup>™</sup> of Stroke Prevention	F
斺 Home	C Refresh Inventory	Generate Rep	oort 🗌 Show (	Queries 🗌 Show	v Disposed				Conform RC	Coordi	nator   Test2 -	TEST2 National Health	Lo
Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	201 Other	
#3250 TEST2	TESTPRODUCT2 - TESTPRODUCT2 - Used for development O-230925081411		TST-201 5/15/2024		12/31/2001								
#3251 TEST2	TESTPRODUCT2 - TESTPRODUCT2 - Used for development 0-230925081411		TST-201 5/15/2024		12/31/2001								
#3252 TEST2	TESTPRODUCT2 - TESTPRODUCT2 - Used for development 0-230925081411		TST-201 5/15/2024		12/31/2001								
#3253 TEST2	TESTPRODUCT2 - TESTPRODUCT2 - Used for development 0-230925081411		TST-201 5/15/2024		12/31/2001								
<b>#3226</b> TEST2	TESTPRODUCT2 - TESTPRODUCT2 - Used for development 0-230912173804		TST-201 5/15/2024		12/31/2001								
#3227 TEST2	TESTPRODUCT2 - TESTPRODUCT2 - Used for development O-230912173804		TST-201 5/15/2024		12/31/2001								
#3228 TEST2	TESTPRODUCT2 - TESTPRODUCT2 - Used for development O-230912173804		TST-201 5/15/2024		12/31/2001								
#2145 TEST2	TESTPRODUCT2 - TESTPRODUCT2 - Used for development		TST-201 5/15/2024		12/31/2001								
9 items Site Numb	per / Name								By selecting this have reviewed th By electronically accept that your the legally bindir	box, you con te above info signing here electronic si te equivalent	nfirm you A primation. , you gnature is tof your	Save Ch	anges

- 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

Devi	ce Accoun	tabilit	y Log / D	tion Up		Inventory Tracking App										
Study Conform	Study Conform Pivotal											COP The Shape	of Stroke Prev			
🕼 Home 🕐 Refresh Inventory 🧮 Generate Report 🔲 Show Queries 🕑 Show Disposed							$\sim$			Conform R	C   Coordi	nator   Test2	- TEST2 N	ational Health	Log O	ut
Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expy Date	Subject ID	Disposition Da	te	<b>₮</b> Deficient	<b>▼</b> Used	<b>▼</b> Disposed	7 Returned	RGA	7 Transferred	Other		×	<u></u>
#2931 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809185754		TST-101 5/15/2023	020	9/6/2023			7		<b>V</b>	450	]	<b>v</b>	FedEx on 9/6/2 555555555	3	-
#2932 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809185754		TST-101 5/15/2023	111	9/12/2023	9/13/20	23 8:27 AM I 0	<b>√</b>	conformalm	edical.com						
#2933 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809185754		TST-101 5/15/2023	007	8/10/2023			2								
#2866 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	$\oslash$	TST-101 5/15/2023	001	8/9/2023			7								



- 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.

Study     Conform Pivotal     Deficient     Conform RC   Coordinator   Test2 - TEST2 National Health     Log       Image: D     Refresh Inventory     Image: D     Show Queries     Show Disposed     Image: D     Conform RC   Coordinator   Test2 - TEST2 National Health     Log       Unique ID     Product Code     Query/     Status     Expy Date     Subject ID     Disposition Date     Cieza National     Filtered by Deficient     Search	
Image: Disposed Product Code Strain Service Product Code State State State Strain Service Product Code State	
Unique D Ste Id Ste Id Ste Id Status Expy Date Product Code Description Status Expy Date Status Expy Date Subject ID Disposition Date Disposition Date Tenform V Used V Disposed V Returned RGA V Transferred Other	Out
	×Q
#3324 TESTPRODUCT3- TST-301 TST-501 TST-301 020 9/25/2023 0 RGA development 0-2309/2501411	
#3147     TESTPRODUCT3 - Used for TESTR     TST-301     003     10/2/2023     Image: Constraint of the second seco	

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.

Devi Study	ce Account	abilit	y Log /	Disposi	tion Ul	odate			Inventory Tracking App conformal <sup>w</sup> to brage of Bala Provertion							
comon	in rivotai															
🔂 Home	C Refresh Inventory	Generate Rep	port 🗌 Shov	Queries 🗹 Sh	ow Disposed	all	$\sim$			Conform I	RC   Coord	inator   Test2 -	TEST2 Na	ational Health	Lo	g Out
Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expy Date	Subject ID	Disposition	Date	7 Deficient		<b>了 Disposed</b>	7 Returned	RGA		Other	Search		×Q
#2931 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809185754		TST-101 5/15/2023	020	9/6/2023			7		~	450	]	7	FedEx on 9/6/2 555555555	3	* *
#2932 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809185754		TST-101 5/15/2023	111	9/12/2023				Valic	lation Erro	ors: 2				$\otimes$	
#2933 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-230809185754		TST-101 5/15/2023	007	8/10/2023			7	#2932 - A disp	TESTPRODUCT osition optio	n must be s	CT - Used for develo selected if a subj	pment ject ID wa	s specified.		
#2866 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	$\oslash$	TST-101 5/15/2023	001	8/9/2023			7	#2932 - At leas	TESTPRODUCT	must be se	CT - Used for develo	pment sed items	5.		
#2867 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819		TST-101 5/15/2023	002	8/9/2023			7								
#2868 TEST2	TESTPRODUCT + TESTPRODUCT - Used for development O-230809184819		TST-101 5/15/2023	002	8/9/2023			7								
#2869 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	۸	TST-101 5/15/2023		8/10/2023											
#2870 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development		TST-101 5/15/2023	003	8/10/2023			~								-
1 / Items Site Num	ber / Name									By selecting th have reviewed By electronica accept that yo	is box, you co I the above in Ily signing her ur electronic s	onfirm you formation. e, you signature is		Save Char	nges	



### 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"

Devi Study Conform	ce Accounta	ability	Log /	Dispos	ition Upda	te				T	CONTC te Shape of St	Iroke Preve		2	
Home Č	) Refresh Inventory 🔠 Ger	inerate Report	Show [	Disposed			Davi	d Houck	Coordinator	21010 - Van	derbilt Univ	ersity M	ledical Cente	Log	Out
roduct Code ite ld	Description Order#	Lot# Expy	Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned			Other	Search		×
<b>30-00214</b> 21010	27mm CLAAS Implant w Delivery System O-220907094627	vith test1 12/3	1/2024	005	12/31/2001		<ul> <li>Image: A start of the start of</li></ul>								-
<b>30-00214</b> 21010	27mm CLAAS Implant w Delivery System O-220907094627	vith test1 12/3	1/2024		12/31/2001										]
<b>30-00214</b> 21010	27mm CLAAS Implant w Delivery System O-220907094627	vith test1 12/3	1/2024		12/31/2001										
<b>30-00214</b> 21010	27mm CLAAS Implant w Delivery System O-220907094627	vith test1 12/3	1/2024		12/31/2001										
<b>30-00214</b> 21010	27mm CLAAS Implant w Delivery System O-220907094627	vith test1 12/3	1/2024		12/31/2001										
<b>30-00214</b> 21010	27mm CLAAS Implant w Delivery System O-220907094627	vith test1 12/3	1/2024		12/31/2001										
<b>30-00214</b> 21010	27mm CLAAS Implant w Delivery System O-220907094627	vith test1 12/3	1/2024		12/31/2001										
30-00214	27mm CLAAS Implant w	vith test1			12/31/2001										٦.
	Delivery System														
5 items Ite Number / 1010 - Var	Name Iderbilt University Medi	ical Center	07.//	Disposi	ition Undat				By selecting this to have reviewed the By electronically s accept that your of the legally binding	e above informa igning here, you electronic signat equivalent of y	ion. ure is pure <b>Tracki</b>	UI ng A	pdate Dis	positio	n
5 items Site Number / 21010 - Var Devic Study Conform Mome	Name Iderbilt University Medi Ce Accounta Pivotal () Refresh Inventory EE	ical Center Ability L	.og / I	Disposi	ition Updat	e			By selecting this to have reviewed the gy electronically is accept that your of the legally binding Inve Conform RC	oox, you confirm e above informa igning here, you electronic signat e enuivalent of y entory	view ure is mure is <b>Tracki</b> Cont The Shape of or   Test2 - 1		pdate Dis pp al <sup>m</sup>		n Out
5 Items Site Number / 21010 - Var Devic Study Conform Mome Unique ID Site Id	Name Iderbilt University Medi Ce Accounta Pivotal C Refresh Inventory E C	ical Center ability L Generate Report Query/ Monitor Lot:	.og /	Disposi	ition Updat	e			By selecting this tendencing that were very were the base reviewed the By electronically a accept that your or the leasely binding the second	expou confirm e above informa igning here, you lectronic signate ecoulvalent of v entory	vyou ure is ure is unir Tracki Cont The Shope o or   Test2 - 1	U ng A Stoke Preve (Stoke Preve	pdate Dis pp cli <sup>m</sup> antional Health Search	Log	n Out
5 Items Ite Number / 1010 - Var Devic Study Conform ŵ Home Unique ID Site Id	Name derbilt University Medi ce Accounta Pivotal C Refesh Inventory Code Description Order# SETPRODUCT - Used for Herelogment	Generate Report Query/ Monitor Status 5/1	.og / I	Disposi Queries SP Subject ID	now Disposed Disposition Date	Ce Deficient	Used	Disposed	By selecting this to have reviewed the have reviewed the By electronically accept that your of the legally binding of the legally binding of the legal bindi	ox, you confirm e above informa- igning here, you electronic signed enuivalent of y enuivalent of y encodinate RGA	you ure is mur Tracki Tracki Trasferred	UI ng A form form form form form form	pdate Dis	Log	n Out
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- 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.

#3282 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-231002102451	TST-101 5/15/2024	12/31/2001				
#3221 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230912173804	TST-101 5/15/2024	12/31/2001				
#3222 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230912173804	TST-101 5/15/2024	12/31/2001				
#3223 TEST2 37 items Site Nun	TESTPRODUCT - TESTPRODUCT - Used for development	TST-101 5/15/2024	12/31/2001		<ul> <li>Hetting this box, you confirm you any reviewed the above information.</li> <li>Hettronically signing here, you cept that your electronic signature is legally binding equivalent of your</li> </ul>	Save Changes	•

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.

Dev	ice Account	abilit	y Log /	Disposition Up	late	Inventor	ventory Tracking App					
Confor	m Pivotal						The shape of shoke inevention					
Home	Refresh Inventory	Generate Re	port 🗌 Sha	w Queries 🔲 Show Disposed		Conform RC   Coordin	ator   Test2 - TEST2 National Health	Log Out				
Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expy Date [				Transferred Other	× 9				
#2872 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819		TST-101 5/15/2023		Login to Continue!	X		*				
#2873 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	~	TST-101 5/15/2023		Conform RC Test2   TEST2 National Health							
#2874 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	~	TST-101 5/15/2023	⑦ Email Address:								
#3281 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-231002102451		TST-101 5/15/2024	Password:								
#3282 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-231002102451		TST-101 5/15/2024		LOGIN							
#3221 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-230912173804		TST-101 5/15/2024									
#3222 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-230912173804		TST-101 5/15/2024									
#3223 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development		TST-101 5/15/2024	12/31/2001								
37 items Site Num -	ber / Name				Ŀ	By selecting this box, you conf have reviewed the above infor By electronically signing here, accept that your electronic sig the leastly binding an ubalent.	irm you mation. you nature is of your	nges				

- 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>°</b> 1						
#2873 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 20809184819	~	TST-101 5/15/2023	12/31/2001			
#2874 TEST2	TEST: LODUCT - TEST RODUCT - Used for Sevelopment 0-230809184819	~	TST-101 5/15/2023	12/31/2001			
#3281 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-231002102451		TST-101 5/15/202 last	modified by (dhouck@conformalmedical.com)	~		

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

Devi Study Conform	ce Account			Inv	entor	y Track	ing Al forme	op al™	R					
🔂 Home	🏠 Home 🖒 Refresh Inventory 🇮 Generate Report 🛛 Show Queries 🗌 Show Disposed								Conform RC	Coordin	ator   Test2 -	TEST2 Na	tional Health	Log Out
Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	ot# expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other	Search	×
#2872 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development 0-230809184819		TST-101 5/15/2023		12/31/2001									*
#2873 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	~	TST-101 5/15/2023		12/31/2001									

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.

Devi Study Conform	<b>ce Account</b> n Pivotal	ability	y Log /	Disposi	tion Update	e			Inv	entor	y Tracki con	ing A form		2	
☆ Home	◯ Refresh Inventory	🗄 Generate Rep	o 🔽 Show	Queries 🗍 Sho	w Dispos				Conform R	:   Coordin	ator   Test2 -	TEST2 N	ational Health	Log	Out
Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expy Date	St ject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other	Search		×Q
#2869 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	۵	TST-101 5/15/2023		8/10/2023				~	555		~	FedEx on 8/10 Tracking #: 12	/23 3456789	
#2876 TEST2	TESTPRODUCT2 - TESTPRODUCT2 - Used for development O-230809184819		TST-101 5/15/2023	003	8/10/2023		~								



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

onitoring - Inventory Query		I.	nventory Tracking App conformal <sup>™</sup> The lape of Stoke Revention	2
<< Back Refresh		Conform	n RC   Coordinator   Test2 - EST2 National Hea	ilth Log O
TEST2 National Health				
2869   TESTPRODUCT   TST-101   5/15/2023				
Last edited by: David Houck   Monitoring Status: -   Disposition Completed on Aug 10, 2023				
Query opened on August 15, 2023 07:26 AM By David Houck	Open	Add response Message		
quary redo	Respond	Type your response here		$\mathbf{\Lambda}$
Query opened on August 24, 2023 11:57 AM By David Houck	Open	Char count 26/400 Minimum 5 characters, maximum 400		. 📥
all good			Cancer	Save
Query opened on September 12, 2023 05:43 PM By David Houck	Open			
answered	Ţ			

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



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#### VIII. **GENERATE REPORTS**

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

Devic Study Conform	e Accountabi	lity Log /	Dispos	ition Updat	е				Conformal <sup>IM</sup> The Shape of Stroke Prevention	2
🔂 Home 🖒	Refresh Inventity 🔠 Geverate F	Report 🗌 Show	Disposed			Dav	id Houck   (	Coordinator	21010 - Vanderbilt University Medical Center	Log Out
Product Code Site Id	Description Order#	Lot# Expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	Search Other	×
<b>30-00214</b> 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001						A
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001						
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001						
<b>30-00214</b> 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001						
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001						

- 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 not 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.

Device Accountability	/ Log Report			Inventory Tracking App conformal <sup>™</sup> The Shape of Steke Pewention	2
🔇 Back			C	Conform RC   Coordinator   Test2 - TEST2 National Health	Log Out
1/1/2022       Image: Completed         Image: Completed description completed       Previously Generated Reports	10/3/2023 🖬 Exclude Monitored	Clear Dates Generate Report	I		
B TEST2_DAL_20231002070928	October 02, 202	3 Developer	View Report	Refresh	
TEST2_DAL_20230913022941	September 13, 2	023 Developer	View Report	Document List	