

CORCYM DEVICE TRACKING SYSTEM

OPERATIONAL INSTRUCTIONS

CC-MK-001118 A

1

How to access Corcym Device Tracking System (1\6)

CORCYM Device Tracking System is accessible at the following address:

http://devicetracking.corcym.com/

 A leaflet reporting the Device Tracking System address, as well as a QR code pointing at it, is included in each device package



Cd Access Code / Codice di accesso del CD / Code d'accès du CD / CD-Zugangscode / Código de acceso del CD / Código de acceso do CD / Toegangscode van de CD / Åtkomstkod för CD-skivan / Tilgangskode for CD'en / Cd-adgangskode / Κωδικός πρόσβασης του CD / Přistupový kód CD / CD juurdepääsukood / CD piekļuves kods / CD prieigos kodas / CD hozzáférési kód / Kod dostępu plyty CD / Koda za dostop do vsebin na CD-ju / Prístupový kód na CD / CD ovíkoodí / CD Erişim Kodu / Cod de accesare a CD-ului / Κοд за достъп до CD / Код доступа компакт-диска / CD 沙 i i 代 任 / Pristupna šifra za CD / Pristupna šifra za CD

DEVICE TRACKING

The Device Tracking is mandatory for United States and Canada only. The Device Tracking Form must be completed by the implanting hospital at the following address:

Le suivi du dispositif est obligatoire pour les États-Unis et le Canada uniquement. Le formulaire de suivi du dispositif doit être rempli par l'hôpital implanteur à l'adresse suivante :

devicetracking.corcym.com



IC0215001373 2023/01/E

How to access Corcym Device Tracking System (2\6)

The system is also accessible through CORCYM website https://corcym.com/
 by selecting the CONTAC US Tab



How to access Corcym Device Tracking System (3\6)

Account Activation

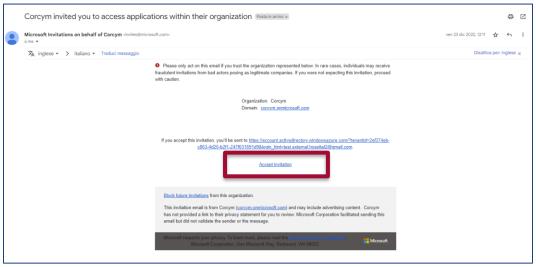
- To gain access to the system, you need to send a request to CORCYM for an account activation by sending an e-mail to <u>customer.qualityhv@corcym.com</u> from your professional e-mail
- In the request, you need to specify the denomination and address of your Institution (hospital/clinic) and the specific department you work in



How to access Corcym Device Tracking System (4\6)

Account Activation

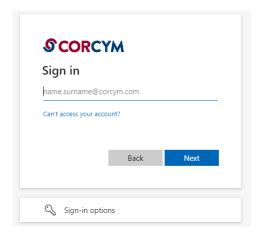
- As soon as your account will be activated, you will receive an e-mail by Microsoft on behalf of CORCYM, with the request to Accept the invitation
- Click on the Accept Invitation Tab



How to access Corcym Device Tracking System (5\6)

Sign-in

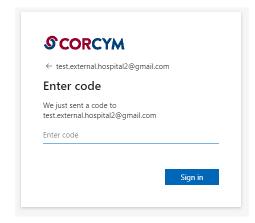
- Sign-in with the e-mail address you have used to request access to the portal
- If you are signing-in with a Microsoft account, you will be prompted to enter your password.
- Your password is the one you use to access your laptop



How to access Corcym Device Tracking System (6\6)

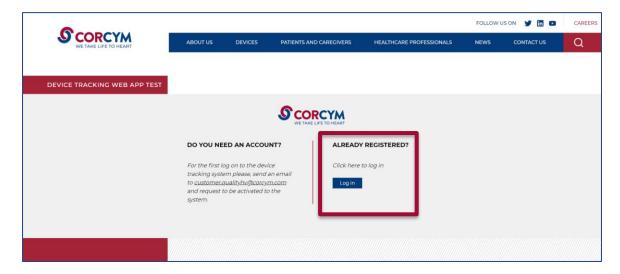
Sign-in

- If you are signing-in with a non-Microsoft account, a single use code will be sent to your mailbox
- Enter this code to sign-in



Log In (1/4)

Once signed-in, you will be able to log into the system by clicking on the Log In Tab displayed at the right on the landing page



Log In (2/4)

Click on the Device Tracking box at the top left of the page



CC-MK-001118 A

Log In (3/4)

At your first access, you will need to acknowledge that you have read and agree with Corcym Privacy Policy. This will be requested at your first log-in only.



CC-MK-001118 A

10

Log In (4/4)

Click on the related link to access Corcym Policy Statement, you will then need to tick the checkbox to record your acknowledgment.



System functionalities

From the main page, you will be able to:

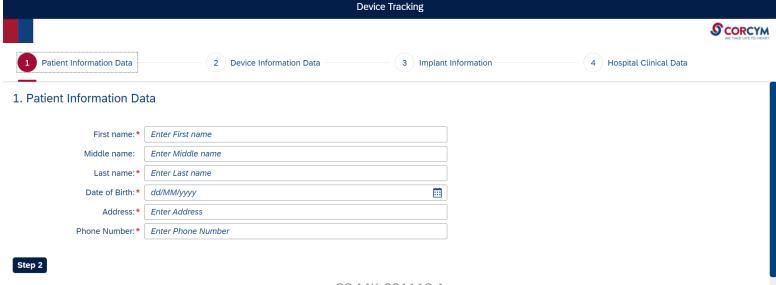
- Enter a new device record (left tab)
- Access the device records created by you or other healthcare professionals in your department who have access to the system (right tab)



New Device Entry Functionality



- Once you access the Device Entry section by clicking on the Start Tab, you will be prompted to enter the patient data first.
- Make sure you fill all the mandatory fields highligthed with a red star



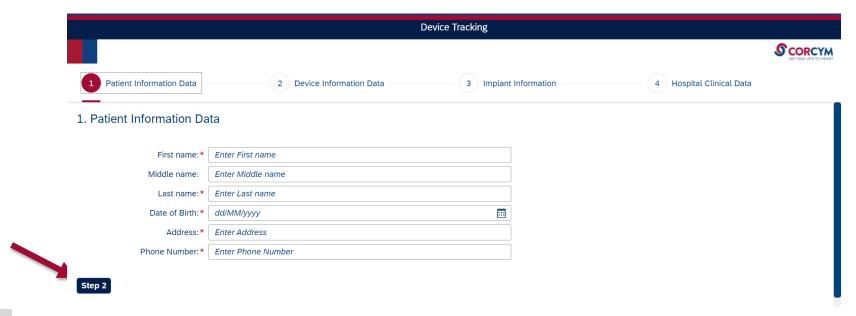
CC-MK-001118 A

14

- To insert the patient's date of birth, select the appropriate date from the calendar which will display by clicking on the corresponding icon
- You can easily navigate the calendar by clicking on the year showing at the top and using the arrows to move to previous or next dates

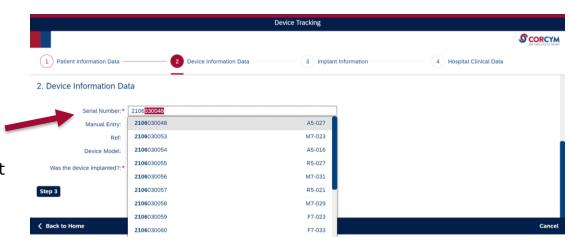


To advance to the next section click on the Step 2 Tab at the bottom left of the screen

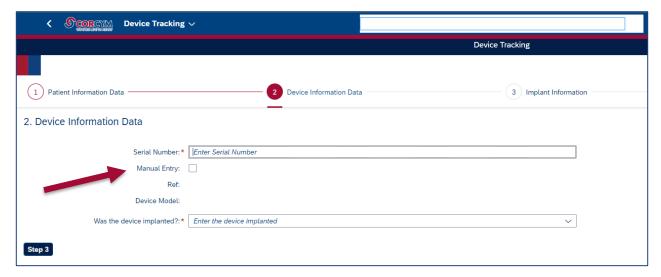


Step 2 requires you to fill in the information related to the device

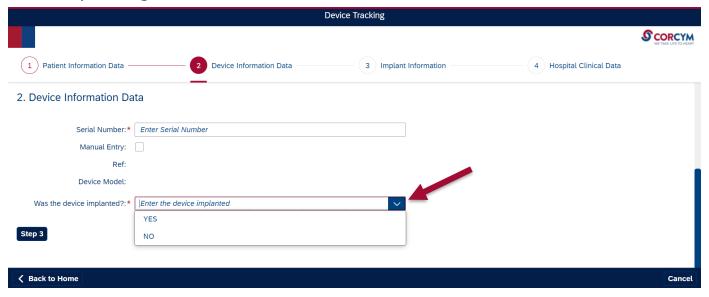
- A lookup funcionality is available to facilitate the device serial number insertion
- Type the first 4 digits of the serial number in the Serial Number box and select the one that applies from the list which will be displayed



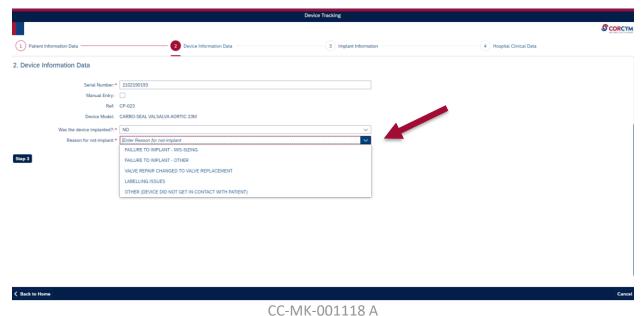
 In case your device serial number doesn't show up, you can add it manually by selecting the corresponding option



- As a further action, you need to confirm if the device has been implanted
- Do so by selecting YES or NO from the drop-down menu which will open by clicking on the arrow in the corresponding box

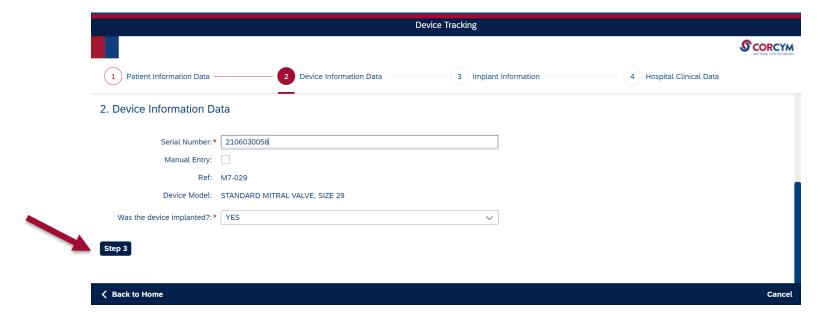


- In case you select NO, you will need to specify the reason why the device was not implanted
- Click on the arrow in the corresponding box and select the one that applies from the dropdown menu which will be displayed



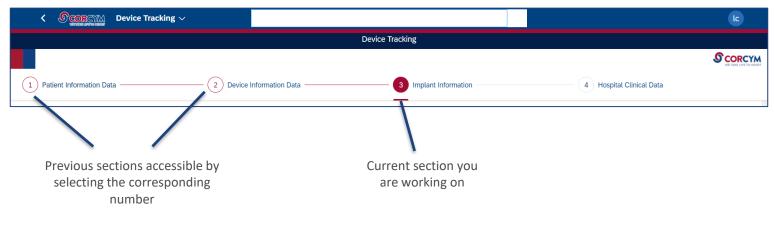
20

To advance to the next section, click on the Step 3 Tab at the bottom left of the screen



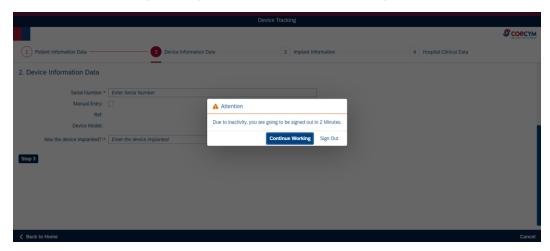
Navigation Tips

- The bar at the top of the screen will display your advancement through the process
- The numbers which identify the sections you have already edited, will turn to red while the current step you are working on will be underlined and highlighted in bold
- In case you need to add or modify any data in the previous sections, you can go back by clicking on the corresponding number until you will enter the Review phase.

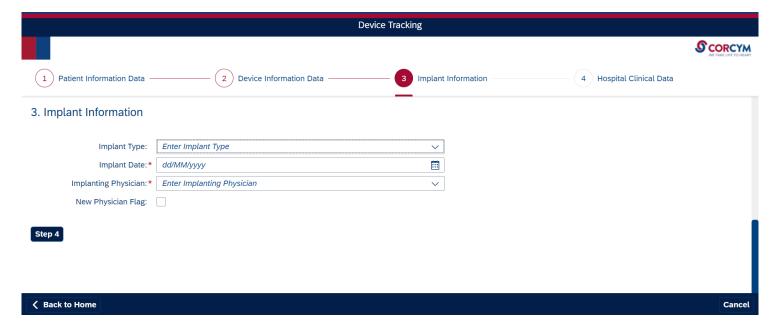


Important Note

- Make sure you have all the needed data on hand while filing a device record since you will not be allowed to save drafts and complete them at a later time
- After 15 minutes of inactivity, a pop-up window will alert that you will be disconnected in 2 minutes
- Click on the Continue Working Tab prior to the timer elapse in order to avoid loosing the data



Step 3 is dedicated to record Implant Information



Device Tracking

 Select the implant type option that applies from the scroll down menu

Enter Implant Type

2 Device Information Data

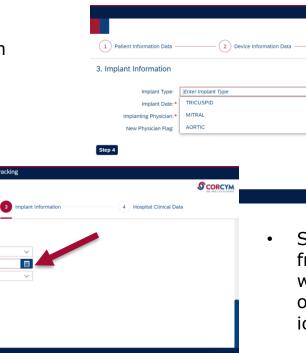
Patient Information Data

3. Implant Information

← Back to Home

Implant Date:*
Implanting Physician:*

New Physician Flag:



Select the implant date from the calendar which will display by clicking on the corresponding icon

Device Tracking

3 Implant Information

CC-MK-001118 A

SCORCYM

4 Hospital Clinical Data

A lookup funcionality is available to upload the Implanting Physician name

1 Patient Information Data

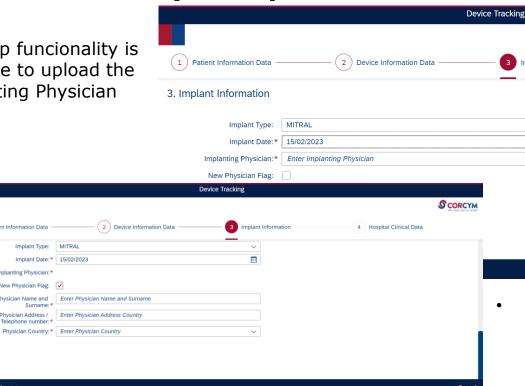
Implanting Physician:* New Physician Flag: Physician Name and

Telephone number: *

〈 Back to Home

Surname: Physician Address /

MITRAL Implant Date: * 15/02/2023



If the Implant Pysician name doesn't display in the list, tick the New Physician Flag box and fill in the requested data

Implant Information

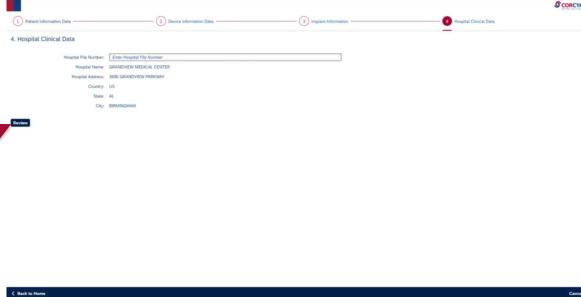
SCORCYM

Cancel

4 Hospital Clinical Data

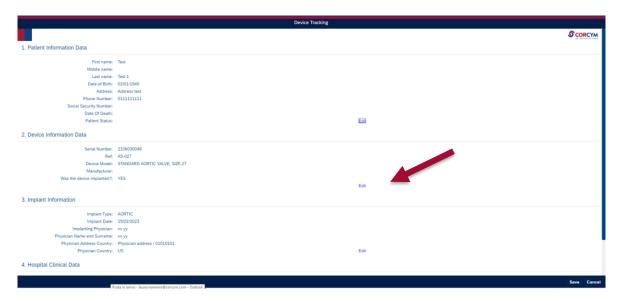
- Step 4 will display your Hospital Name and Address
- You can add your Hospital File Number

As a next step, go to the Review phase by clicking on the corresponding Tab



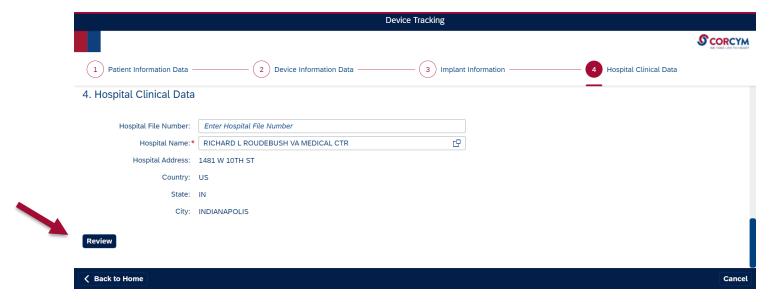
Review Section

- The Review page will provide an overview of all the information included in each section
- In case you need to add or modify any data, access the related section by clicking on the Edit
 Tab at the right



Review Section

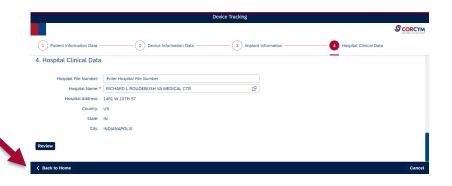
- Once you have modified the field/fields of interest, click the Review Tab at the bottom left to access again the Review screen
- You might need to scroll down the page to display the Review Tab



Review Section - Note

• In case you press the **Back to Home** Tab by mistake , you will be directed to the main page





 By accessing the New Device Entry Section, you will be directed to the section that you were modifying

How to submit the device record

Once you are ready to submit the record, click **Save** on the menu bottom right

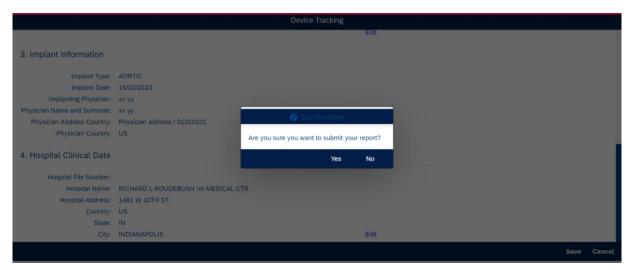
Device Tracking			
		Edit	
3. Implant Information			
Implant Type:	AORTIC		
Implant Date:	15/02/2023		
Implanting Physician:	хх уу		
Physician Name and Surname:	хх уу		
	Physician address / 01010101		
Physician Country:	US	Edit	
4. Hospital Clinical Data			
Hospital File Number:			
Hospital Name:			
Hospital Address:			
Country:	US		
State:	IN		
City:	INDIANAPOLIS	Edit	
			Save Cance

CC-MK-001118 A

31

How to submit the device record

- Since this action is irreversible, a pop-up window with a warning message will display
- Select NO if you want to take a further review, YES to submit your record. A message will
 confirm that the record has been successfully saved.



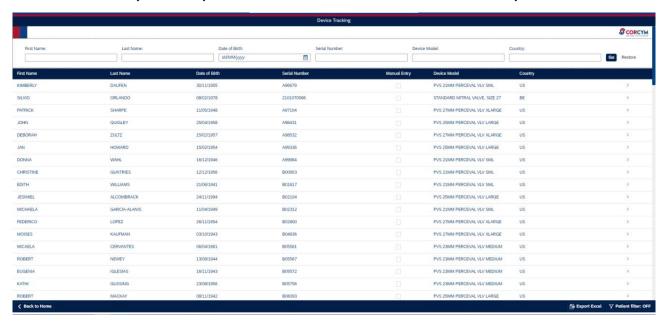
NOTE: Once a record has been submitted you will not have the possibility to apply any changes. In case you need to correct or add any information, reach out to Corcym through the Contacts reported at the end of this document

Existing Device List Functionality



Existing Device List Main Page

By entering the Existing Device List, you will have access to all the records created by you or other healthcare professionals in your department who have access to the system



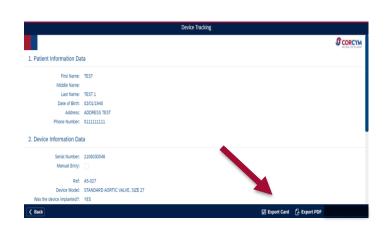
Existing Device List Main Page

- From the menu at the top of the page, you can search a specific record by serial number, patient name or date of birth. You can also filter by device model.
- To perform a search, insert the data in the appropriate box and click on the **Go** Tab.
- Click on the **Restore** Tab to display all the records after a search



Patient card

- By accessing a specific record, you will be able to export the Patient card in pdf format.
- To export the card, click on the corresponding tab bottom right.
- Patient card is available both in English and French language.





36

Reports

 By clicking on the Export PDF Tab, a pdf file including all the information contained in the specific record you have accessed will be generated and available to be saved or printed.





Contacts

For any inquiry on Corcym Device Tracking System or in case you experience technical issues, you can choose one of the following options:

- Send an e-mail to <u>customer.qualityhv@corcym.com</u>
- Call 1-866-691-0033 for US or 1-832-699-1232 (ON/QC) for Canada