

Persona IQ[®]
THE SMART KNEE[™]

CANARY canturio[®] Tibial Extension
with CHIRP[®] System

**Using the OR Base
StationQuick Start Guide**

Read this manual carefully. If you have additional questions after reading this manual, contact Canary Medical.



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1. OR Base Station Equipment

Canary Operating Room Base Station Equipment			
OR Base Station Unit	USB Connector	PC with Canary Medical™ OR App	Barcode Scanner

2. Pre-Operative: Setting Up the OR Base Station and Testing the Canturio™ Tibial Extension (CTE)

TECHNIQUE TIP: To streamline surgical flow, test the CTE implant prior to entering the OR.

WARNING: Retain the CTE implant in its packaging box. **DO NOT** remove the CTE implant from the packaging box until it has successfully passed Self-Test and Sensor Check and is ready to be introduced into the sterile field.

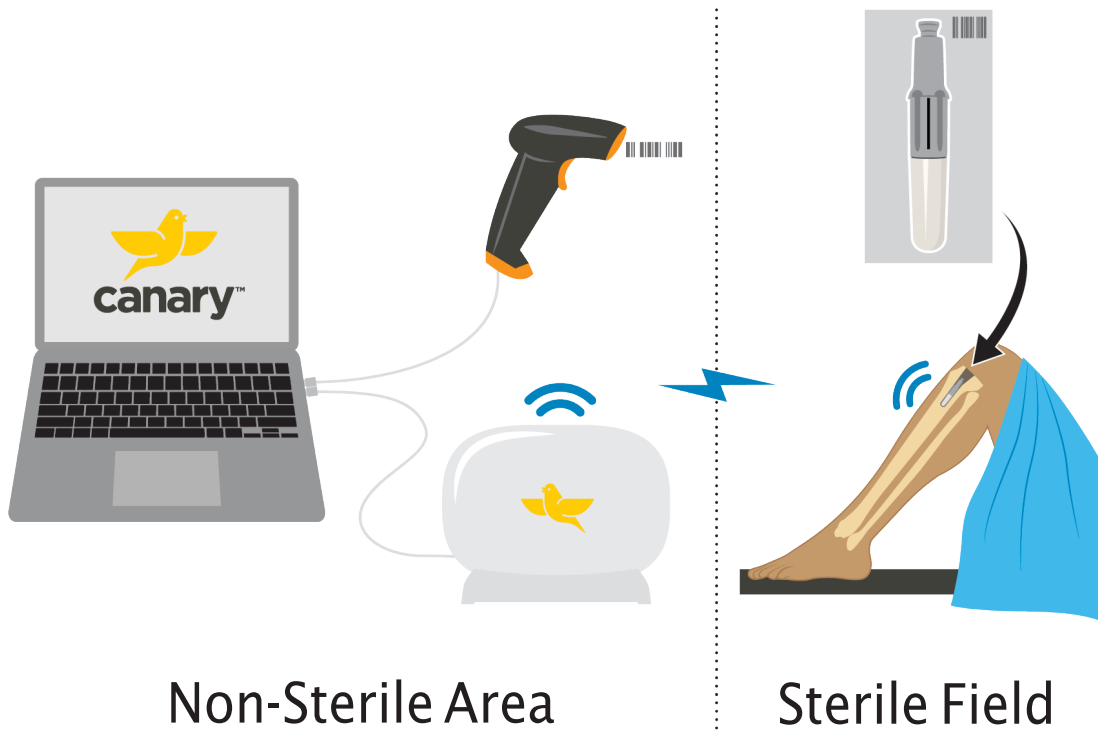
Use the steps below to set up the OR Base Station and test the CTE implant.

NOTE: The OR App will not function and you will not be able to log in without first connecting the OR Base Station to the Laptop.

1. Turn on the Canary Medical Laptop in an area with access to Wi-Fi.
2. Gather a CTE implant, the OR Base Station Unit, Bar Code Scanner, and USB cables.
 - a. Check the expiration date on the CTE implant package to ensure the implant is not expired.

WARNING: To avoid potential patient injury, do not use the CTE implant if it is expired.

NOTE: Do not open the CTE package at this time.



3. Set up the OR Base Station system in or near the OR but outside the sterile field, using the steps below:
 - a. Place the Base Station stand on a flat surface. Place the Base Station into the stand as shown in Figure 1. Insert the provided screw through the groove in the stand into the Base Station. Tighten the screw with a screwdriver.



Figure 1: Base Station in Stand – Rear View

- b. Connect the USB cable to the OR Base Station on one end and the Laptop PC on the other, as shown in Figures 2 and 3.



Figure 2



Figure 3

- c. Connect the Barcode Scanner to the Laptop.
4. On the Canary Medical laptop, the Canary Medical™ Operating Room Application (OR App) will start automatically, and you will see the image of an implant in the center of the screen.
 5. Ensure the OR Base Station and Laptop are connected. This is indicated by the green “Base Station” icon at the top of the Laptop screen. See Figure 4.
 6. Ensure an Internet connection has been established and the OR App is connected to the Canary Medical™ Cloud. This is indicated by the green Internet icon at the top of the Laptop screen. See Figure 4.

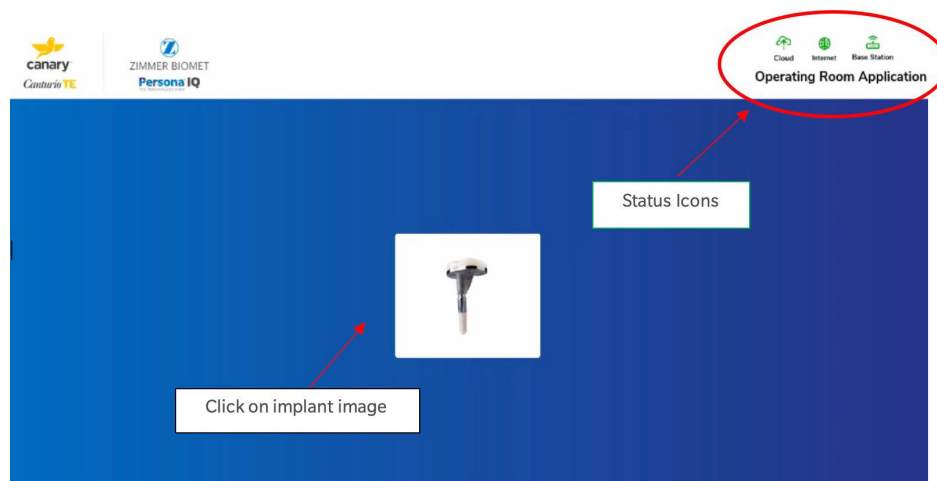


Figure 4

7. Click on the image of the implant in the center of the screen. The login screen will appear. See Figure 5.

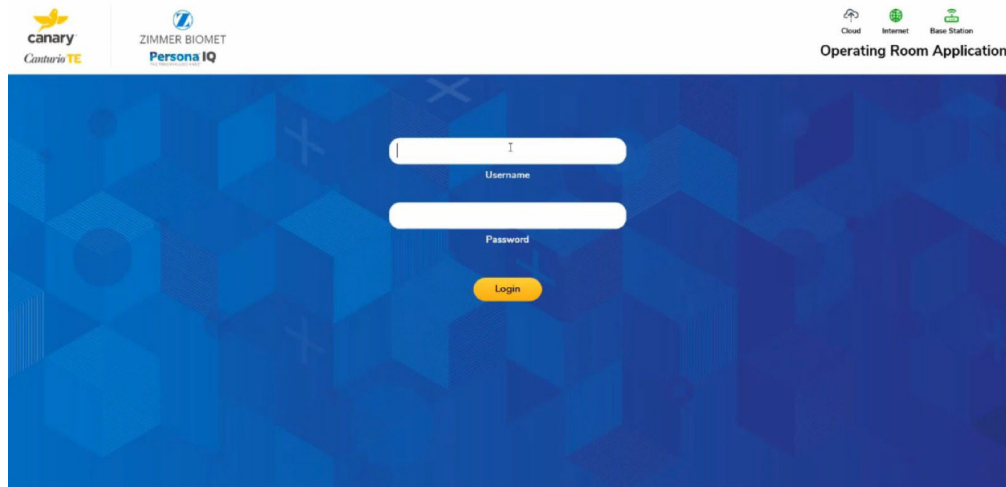


Figure 5: Login Screen

8. Enter your authorized Username and Password and click the “Login” button. This will take you to the Main Menu screen. See Figure 6.

NOTE: A sync to the Cloud will automatically occur after the Internet connection is established and the user is logged in. A sync ensures the most recent patient data is loaded. The Cloud icon at the top of the Laptop screen will indicate the sync status and time of last successful sync. Place the CTE implant package’s large face on a flat surface within 6 feet of the OR Base Station that is connected to the Laptop.

NOTE: Placing the CTE implant (within package) more than 6 feet from the OR Base Station or having any large metal objects between or near the components can interfere with communication between the devices.

9. On the Main Menu screen, under “Preoperative,” click on the “Setup Implant” icon. See Figure 6.



Figure 6: Main Menu

10. Click in the text box and enter or scan the CTE serial number from the implant package. Click “Ok.” See Figure 7.

NOTE: If scanning, place the barcode scanner over the 2D bar code, as shown in the example image below.

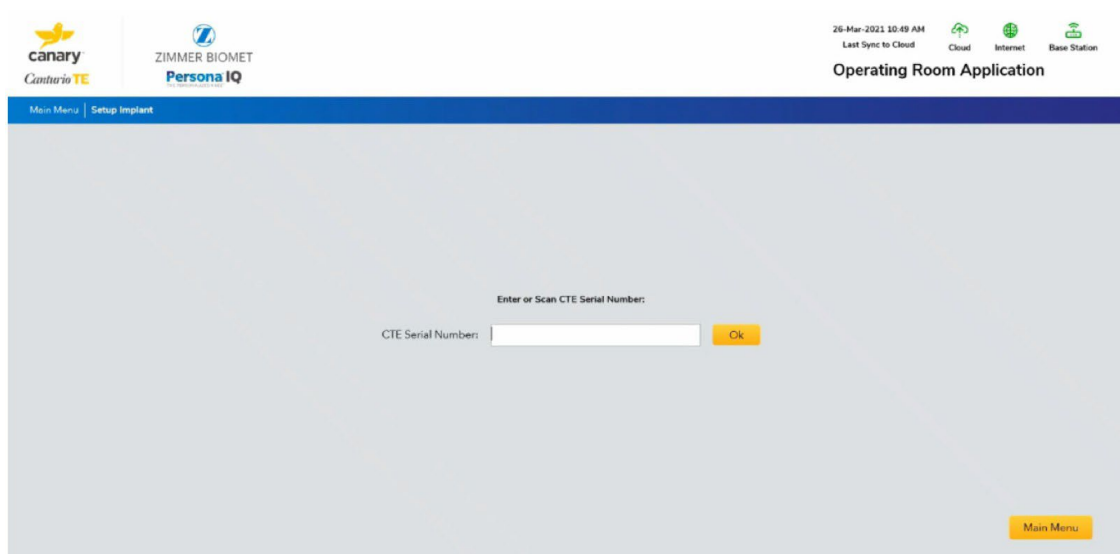


Figure 7: Enter or Scan CTE Serial Number

11. The CTE implant initiates communication with the OR Base Station. Click “Ok” when this process is finished. See Figure 8.



Figure 8

- a. Click on Self-Test. See Figure 9. Upon initiation of a Self-Test the internal CTE electronics perform a series of self-tests and system communication integrity checks for all essential functions. If any of the self-tests fail, the microcontroller will log a permanent and specific error code in memory. These logs are then uploaded and evaluated. A “pass” result is only possible if all self-tests were successfully passed. If any of the self-tests failed or if any other non-passing log was generated since the time of manufacturing, a “fail” result will be displayed.

NOTE: It is possible for a “Time Out” message to be displayed if a wireless connection could not be established between the Base Station and CTE implant due to proximity or interference. If the Self-Test takes more than 15 seconds to display a result, then lack of wireless communication may be the cause. Re-attempt Self-Test after ensuring the CTE implant and Base Station are a) within 2 meters of each other, b) not near large metal objects such as metal tables or metal shelves and c) are not near Wi-Fi radiators such as mobile phones or computers. If the Self-Test continues to display a “Time Out” message, do NOT unpackage the device and contact Canary Medical at 1-833-722-6279 for Return Authorization.

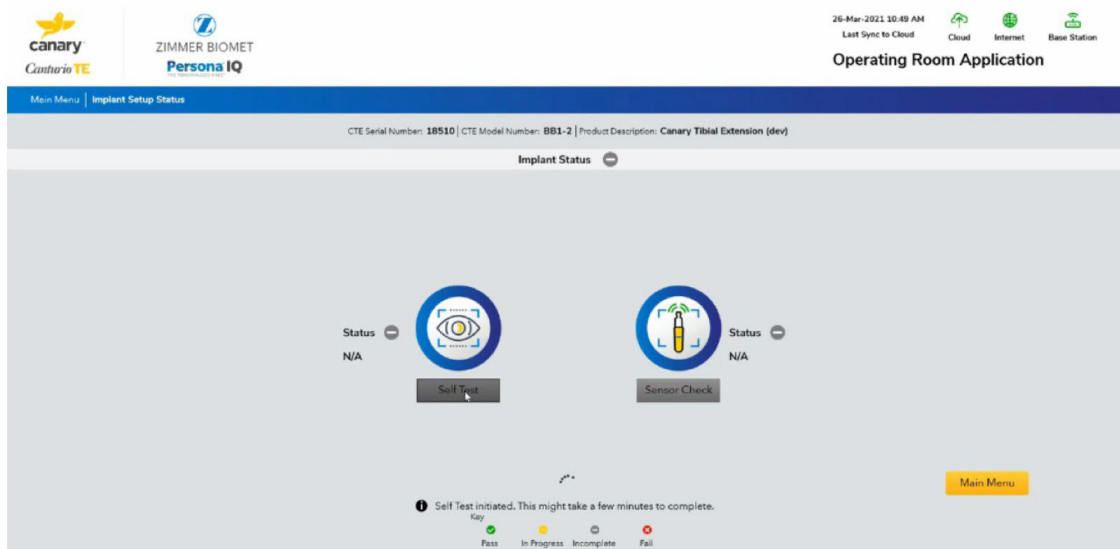


Figure 9: Self-Test

- b. Click on Sensor Check. See Figure 10. Upon initiation of a Sensor Check the IMU in the CTE captures a brief series of accelerometer and gyroscope (gyro) data which is then evaluated relative to the normal range for as-manufactured devices. A “pass” result is only possible if both accelerometer and gyro data are within the normal range.

NOTE: It is possible for a “fail” result to be displayed if the CTE was not stationary during the Sensor Check. Re-attempt Sensor Check after ensuring the CTE is stationary for 10 seconds after starting Sensor Check. If the Sensor Check continues to display a “fail” result, do NOT unpackage the device and contact Canary Medical at 1-833-722-6279 for Return Authorization.

NOTE: It is possible for a “Time Out” message to be displayed if a wireless connection could not be established between the Base Station and a) within 2 meters of each other, b) not near large metal objects such as metal tables or metal shelves and c) are not near Wi-Fi radiators such as mobile phones or computers. If the Sensor Check continues to display a “Time Out ” message, do NOT unpackage the device and contact Canary Medical at 1-833-722-6279 for Return Authorization.

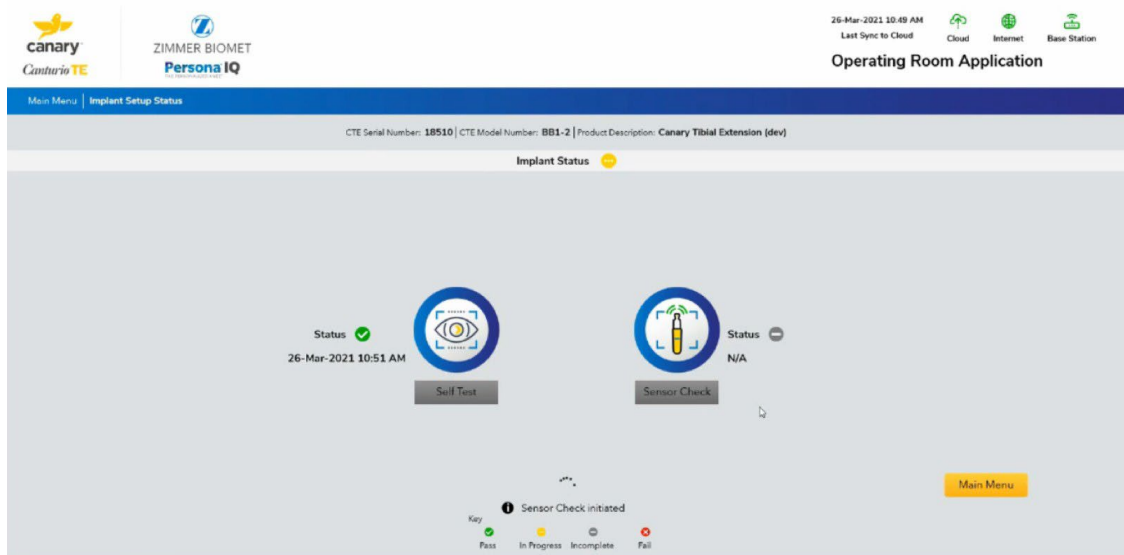


Figure 10: Sensor Check

- When the Self-Test and Sensor Check are successful, the CTE implant is ready to be used for the patient's TKA surgery. See Figure 11.

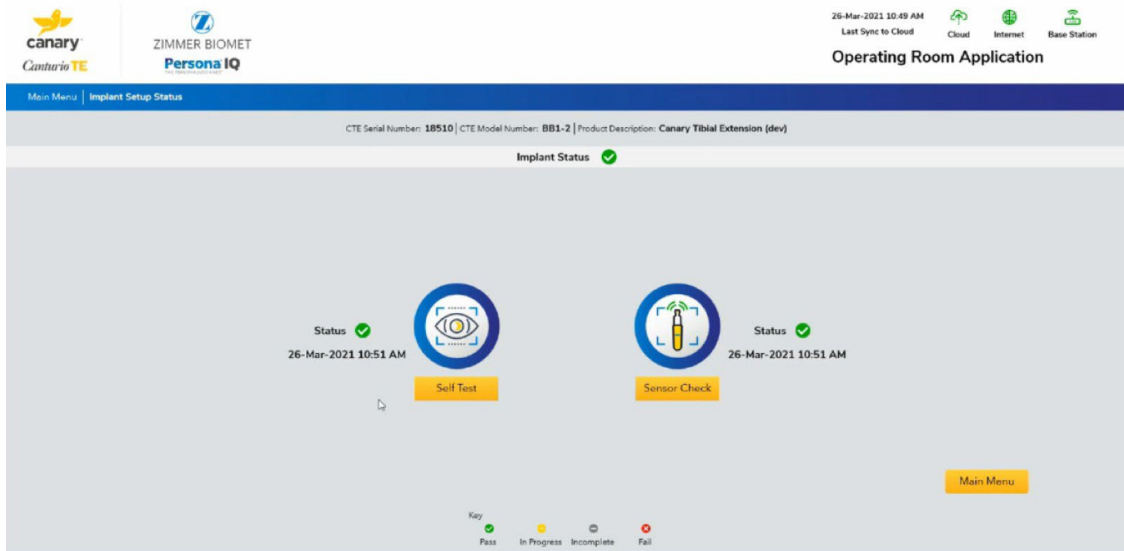


Figure 11: Self-Test and Sensor Check Successful

If the Self-Test and Sensor Check have been run successfully within the last 24 hours, the status will reflect that, and the user can elect to not repeat these tests.

3. Activating the CTE Implant

After the CTE implant has been introduced into the sterile field, and before assembly with the Persona tibial plate, use the steps below to activate the CTE implant.

1. Place the OR Base Station within 6 feet of the CTE implant. Connect the USB cable to the OR Base Station and Laptop. Connect the Barcode Scanner to the Laptop.
2. Plug the Laptop into a power outlet (if needed) and turn on the Laptop.
3. The Canary Medical™ Operating Room Application (OR App) will start automatically.
4. Ensure the OR Base Station and Laptop are connected. This is indicated by the green “Base Station” icon at the top of the Laptop screen.
5. Ensure an Internet connection has been established and the OR App is connected to the Canary Medical™ Cloud. This is indicated by the green Internet and Cloud icons at the top of the Laptop screen.
6. Click on the image of the implant in the center of the screen.
7. Enter your authorized Username and Password and click the “Login” button. This will take you to the Main Menu screen. See Figure 12. Click on the “Activate Implant” Icon.

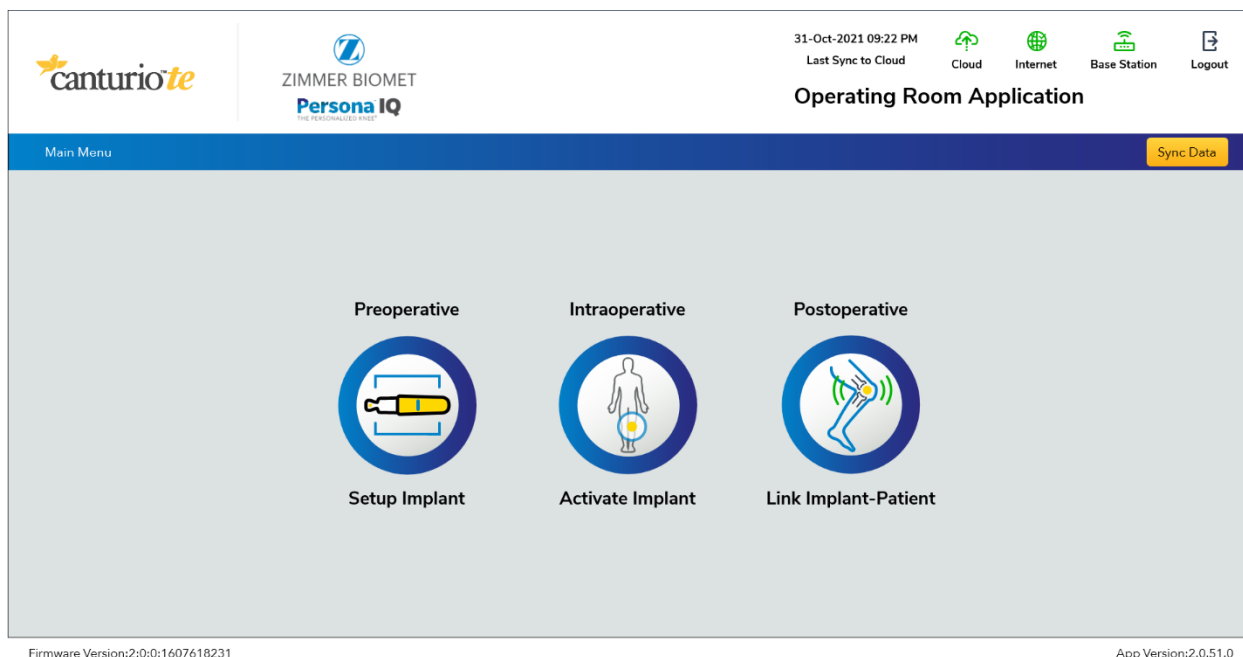


Figure 12: Main Menu

8. Click in the text box and enter or scan the CTE Serial Number, then click “OK.” See Figure 13.

NOTE: If scanning, place the barcode scanner over the 2D bar code as shown in the example image below.



Figure 13: Enter or Scan CTE Serial Number

9. Click “Activate.” See Figure 14.

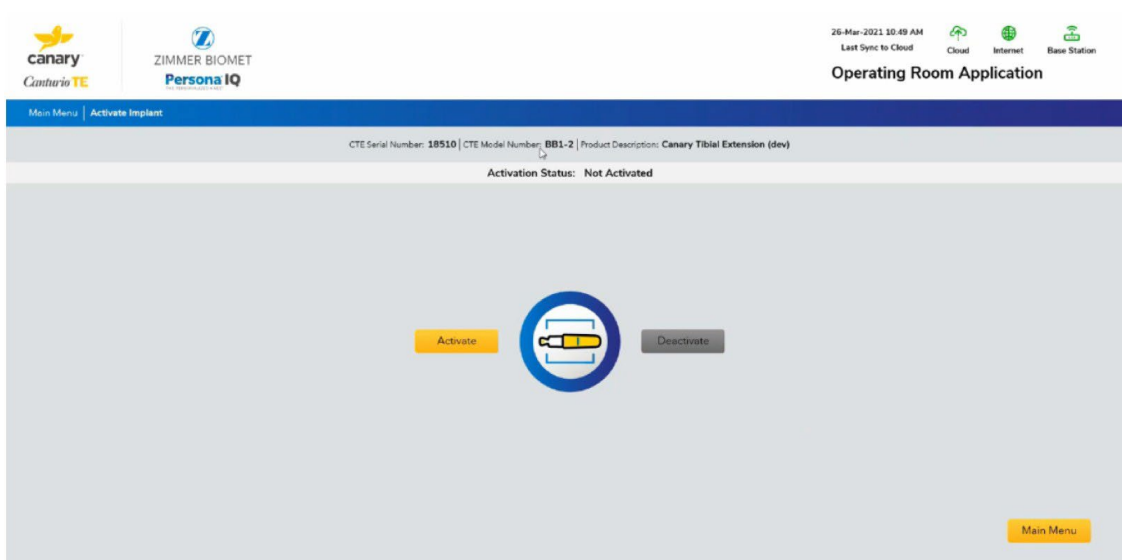


Figure 14: Activate

4. Linking the CTE to the Patient

After the surgery is complete, use the OR PC Application and Barcode Scanner to link the patient's CTE to the patient's account.

1. Connect the USB cable to the Base Station and Laptop. Connect the Barcode Scanner to the Laptop.
2. Plug the Laptop into a power outlet (if needed) and turn on the Laptop.
3. The Canary Medical™ Operating Room Application (OR App) will start automatically.
4. Ensure the OR Base Station and Laptop are connected. This is indicated by the green “Base Station” icon at the top of the Laptop screen.
5. Ensure an Internet connection has been established and the OR App is connected to the Canary Medical™ Cloud. This is indicated by the green Internet icon at the top of the Laptop screen.
6. Click on the image of the implant in the center of the screen.
7. Enter your authorized Username and Password and click the “Login” button. This will take you to the Main Menu screen. See Figure 15.
8. Under “Postoperative,” click on the “Link Implant – Patient” icon. See Figure 15.

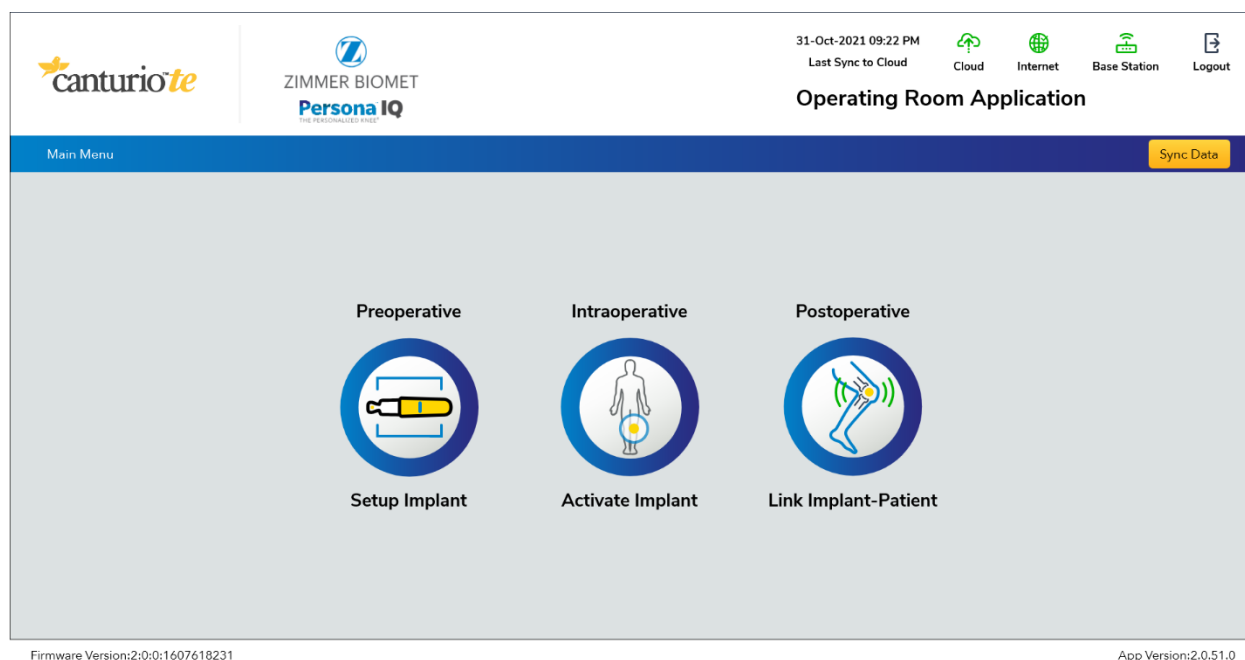


Figure 15: Main Menu

9. Choose the patient's name from the Patient List. See Figure 16.

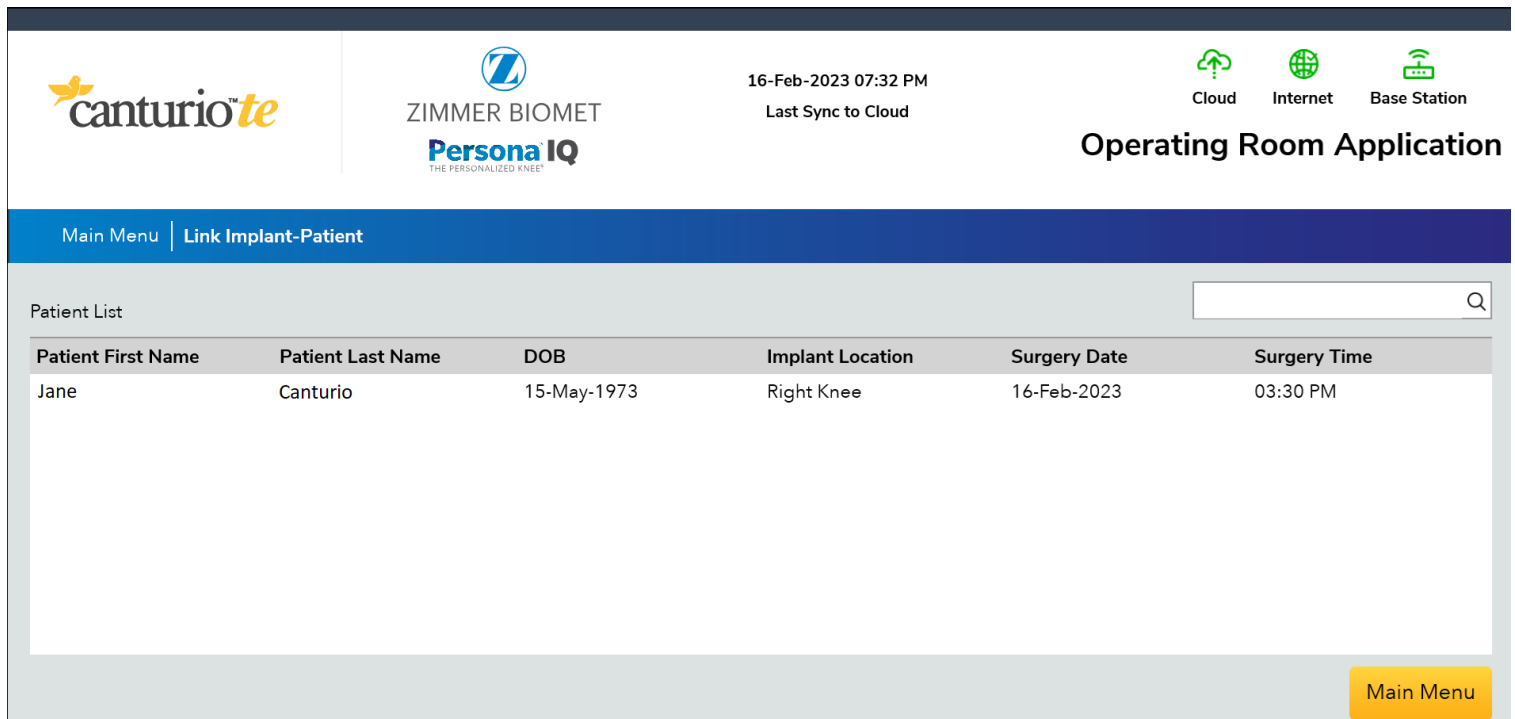


Figure 16: Choose Patient from List

10. Click in the text boxes to enter or scan the serial number of the CTE. When finished, click “Submit” to save the information to the patient’s account. See Figure 17.

NOTE: If scanning, place the barcode scanner over the 2D bar code on the label, as shown in the example image below.

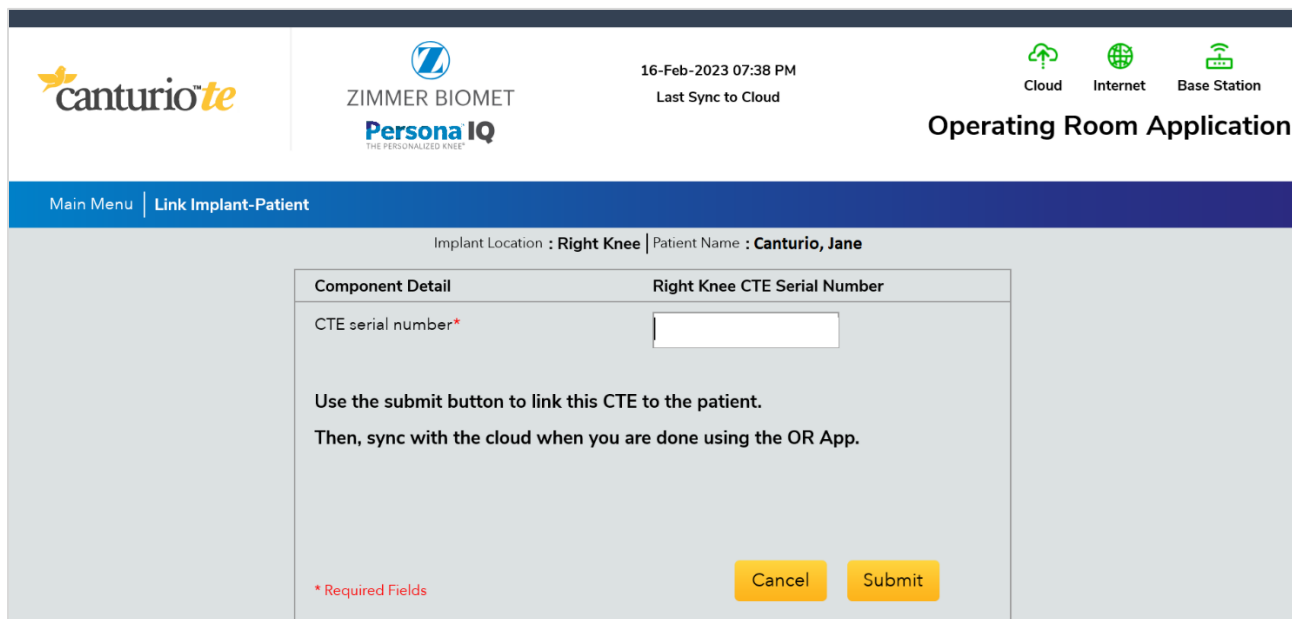


Figure 17: Add Component Information

11. The OR App will display pending CTE link and cloud sync actions in red text at the top of the application window. See Figure 18 for an example.

The screenshot displays the top header of the 'Operating Room Application'. On the left, the 'canturio^{te}' logo is shown. In the center, the 'ZIMMER BIOMET Persona IQ' logo is present, with the tagline 'THE PERSONALIZED KNEE'. To the right of the logo, the text reads '16-Feb-2023 07:38 PM' and 'Last Sync to Cloud'. Below this, a red message states: '1 CTEs have been linked and are awaiting sync with the cloud'. Further right, there are three status icons: 'Cloud', 'Internet', and 'Base Station'. The application title 'Operating Room Application' is positioned on the far right of the header.

Below the header is a navigation bar with 'Main Menu' and 'Link Implant-Patient' options. The main content area is titled 'Patient List' and includes a search bar. A table with the following columns is shown: 'Patient First Name', 'Patient Last Name', 'DOB', 'Implant Location', 'Surgery Date', and 'Surgery Time'. The table is currently empty, displaying the message 'No Records Found'. A 'Main Menu' button is located in the bottom right corner of the application window.

Figure 18: CTE Link and Cloud Sync Status



To learn more about Persona IQ®,
email SmartKneeSupport@zimmerbiomet.com
or call 844-799-8208.

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HCP Canturio is an imaginary health care provider with a fabricated surname.
Jane Canturio is an imaginary patient with a fabricated surname.

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canturio™ Manufactured for:
Canary Medical USA LLC
2710 Loker Ave. West, Suite 350
Carlsbad, California 92010
Customer Service: 1-833-722-6279 or 1-833-
7CANARY www.canarymedical.com

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PN K01-ORBS-300003, Rev. E