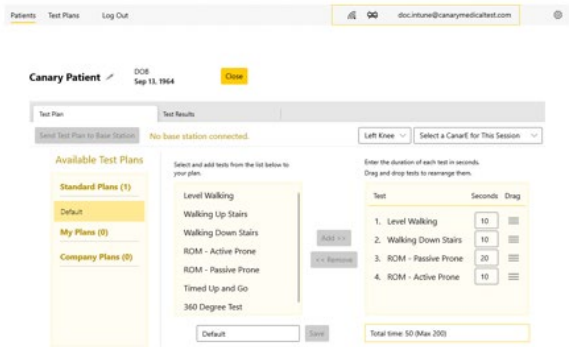




Clinic Base Station System Quick Start Guide



Read this guide carefully. If you have additional questions after reading this guide, refer to the Instructions for Use or contact Canary Medical.



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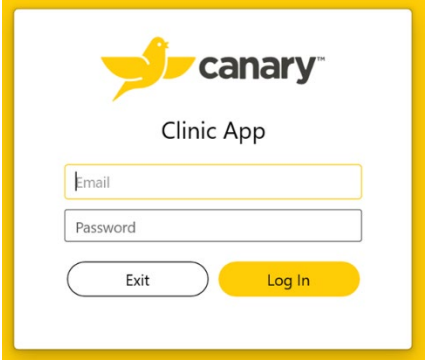
1. System Components and Setup

1.1. Clinic Base Station System Components:

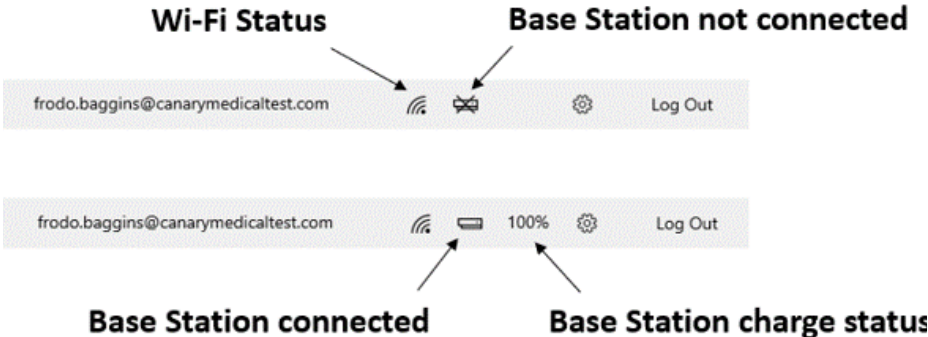


1.2. Getting Started – Clinic Laptop and Clinic App:

1. Turn on the Laptop and verify that the Laptop has established a Wi-Fi internet connection. Charge the Laptop with the supplied power cord in needed.
2. Launch the Canary Clinic App if it does not automatically open.
3. Enter your Canary Username and Password to log in to the Clinic App



- 4. The Clinic App displays the Wi-Fi connectivity status, the Clinic Base Station connection status, and the Clinic Base Station charge status if connected.



1.3. **Getting Started – Clinic Base Station:**

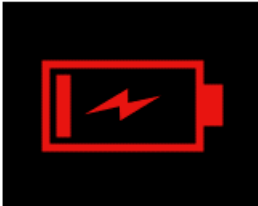
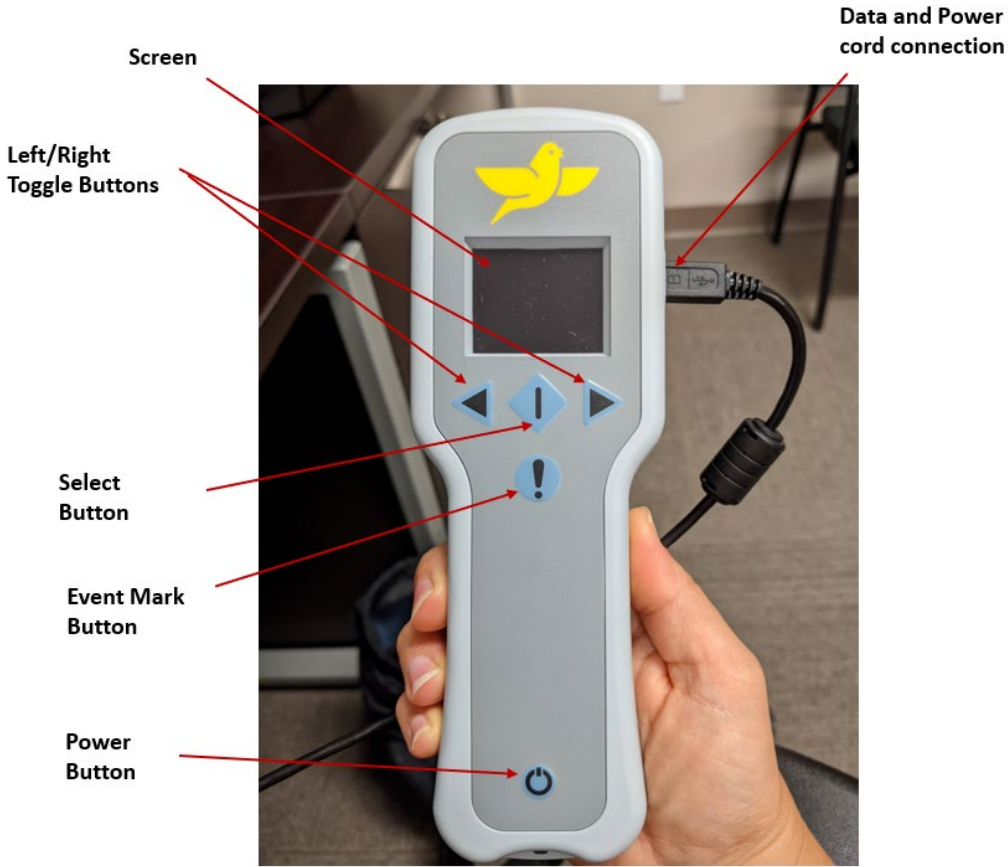
- 1. The Clinic Base Station power cord is a USB cable that may be connected to either the supplied wall power adapter or directly to the Laptop to charge it
- 2. Connect the Clinic Base Station to the Laptop with the USB cable. Press the Power button to turn it on

NOTE: Only connect one (1) Clinic Base Station to the Laptop at a time

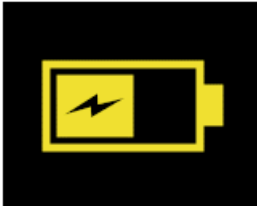


USB connection port

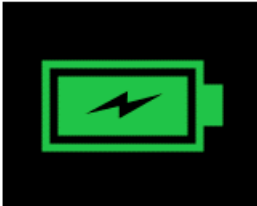




Charging Red:
Battery < 20%



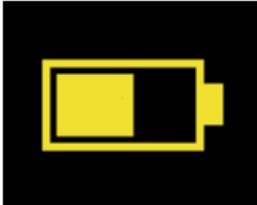
Charging Yellow:
Battery between 20-40%



Charging Green:
Battery > 40%



Not Charging Red:
Battery < 20%



Not Charging Yellow:
Battery between 20-40%



Not Charging Green:
Battery > 40%



2. Create a Test Plan on the Clinic App

1. Open the Clinic App and click the **Test Plans** tab.
2. A Default Test Plan is available to use or a customized Test Plan can be created, saved to your Canary Account, and then used for any selected patient.
3. To create a customized Test Plan, select the desired test(s) from the Test Options list then click **Add** to add the tests you would like to perform.

NOTE: Tests can be removed from the Test Plan by selecting the test within the Test Plan then clicking **Remove**.

NOTE: A maximum of nine (9) tests can be saved to a Test Plan.

4. Drag and drop the different tests within the Test Plan to set the order in which tests will be displayed on the Clinic Base Station.

NOTE: Tests can be selected in any order on the Clinic Base Station during patient evaluation if a change is needed.

5. Set the Test Duration time in seconds for each test within the Test Plan. This will be the duration of time the patient's CTE Implant or CanarE device collects kinematic data while the patient performs the selected test.

TIP: Verify that the data collection times are set so that the patient can complete the prescribed test in the set amount of time.

NOTE: The Clinic App will not allow you to save or perform a test plan that exceeds the maximum collection time. This is to ensure that the CTE Implant or CanarE device battery is not depleted before its expected service life.

6. To save a created custom Test Plan to your account under the **My Plans** header, enter a name for the customized test plan and click **Save**. This plan will be saved to your account and can be used for any of your patients as

NOTE: Other HCPs who create custom test plans within your same clinic account can use them for any of your other patients by selecting the Test Plan under the **Company Plans** header, and then used for any selected patient.

canary Patients **Test Plans** frodo.baggins@canarymedicaltest.com [Signal] [Volume] [Settings] Log Out

Test Plans

Saved Test Plans

1. You may select and modify any test plan below or create a new test plan on the right.

STANDARD PLANS (1)

- Default

MY PLANS (20)

- Gait LWRAUP
- Gait RU
- Gait TRA
- Gait WRU
- Gait WRU_1

Test Options

2. Select tests from the list below to add them to your test plan.

TESTS

- Level Walking
- Walking Up Stairs
- Walking Down Stairs
- ROM - Active Prone
- ROM - Passive Prone
- Timed Up and Go
- 360 Degree Test

Test Plan

3. Enter the duration of data collection for test in seconds. Drag and drop tests to reorder them.

Add >>

<< Remove

TEST	SECS	DRAG
1. Level Walking	10	≡
2. Walking Up Stairs	10	≡
3. Walking Down Stairs	10	≡
4. ROM - Active Prone	15	≡
5. ROM - Passive Prone	15	≡
6. Timed Up and Go	20	≡
7. 360 Degree Test	10	≡

Test Plan Name: Default

Save Plan

Total time: 90 (Max 180)

Default Test Plan

canary Patients **Test Plans** frodo.baggins@canarymedicaltest.com [Signal] [Volume] 100% [Settings] Log Out

Test Plans

Saved Test Plans

1. You may select and modify any test plan below or create a new test plan on the right.

STANDARD PLANS (1)

- Default

MY PLANS (20)

- 10 sec walking
- Gait LWRAUP
- Gait RU
- Gait WRU_1
- Gait WRU_2

Test Options

2. Select tests from the list below to add them to your test plan.

TESTS

- Level Walking
- Walking Up Stairs
- Walking Down Stairs
- ROM - Active Prone
- ROM - Passive Prone
- Timed Up and Go
- 360 Degree Test

Test Plan

3. Enter the duration of data collection for test in seconds. Drag and drop tests to reorder them.

Add >>

<< Remove

TEST	SECS	DRAG
1. Level Walking	10	≡
2. Level Walking	10	≡

Test Plan Name: 10 sec walking

Save Plan

Total time: 20 (Max 180)

Test Plans saved under current logged in user

Add/Remove Test

Set Test Duration

Drag to arrange tests

Name and Save Custom Test Plan



Test Plans

Saved Test Plans

1. You may select and modify any test plan below or create a new test plan on the right.

MY PLANS (20)

- WAPU
- WAU 10
- WAU 10ss
- WAU 5s
- COMPANY PLANS (4)**
- Gait
- GAIT WRAU
- Downstairs 20s**
- RAU2

Test Options

2. Select tests from the list below to add them to your test plan.

TESTS

- Level Walking**
- Walking Up Stairs
- Walking Down Stairs
- ROM - Active Prone
- 360 Degree Test

Test Plan

3. Enter the duration of data collection for test in seconds. Drag and drop tests to reorder them.

TEST	SECS	DRAG
1. Walking Down Stairs	20	≡

Test Plan Name: Downstairs 20s

Save Plan

Total time: 20 (Max 180)

All Test Plans created within HCP organization

Total Test Plan data collection time and max time allowed

Total time: 20 (Max 180)



3. Download a Patient Test Plan to the Clinic Base Station

3.1. Select a Patient in the Clinic App

1. Click the **Patients** tab.
2. Click within the text box, and then type the first three (3) or more letters of the patient’s first or last name. Search results will be displayed.
3. Click the desired patient name.

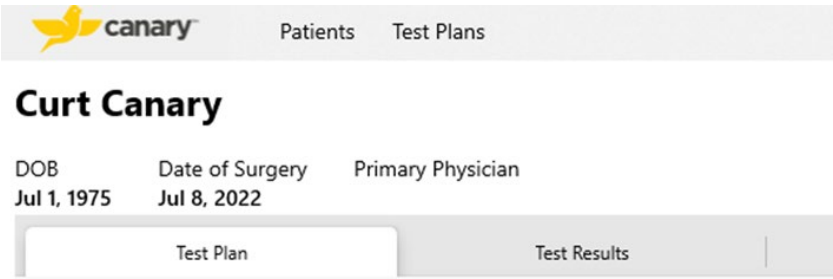
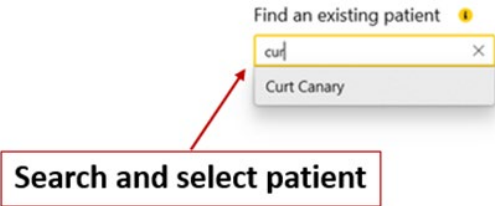
NOTE: The patient must have a Canary account previously created at the time they received their CTE Implant or from their account previously created in the Clinic App.

4. If the patient is new, select **Create a New Patient** and then follow the steps in Section 3.2.
5. Verify that the displayed patient information is correct for the desired patient. If the patient has received a CTE Implant, it will be automatically selected and displayed.

NOTE: If the patient has bilateral implants, select **CTE** and then **Left Knee** or **Right Knee** from the drop-down list.

NOTE: If any information displayed is incorrect, contact your Admin User or Canary Medical Support.

Patient Search



3.2. Creating a New CanarE Patient in the Clinic App

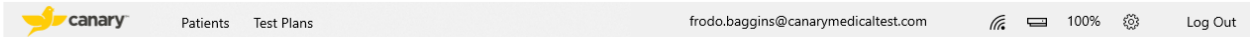
1. Click the **Create a New CanarE Patient** button.

NOTE: If the new patient created is intended to receive a CTE, you can create their patient account within the Physician Dashboard following the CTE with CHIRP System IFUs (K01-CTE-300004 and K01-HBS-300003). Alternatively, follow the steps in Section 3.2.2 to enroll a patient for a Canary CTE Implant within the Clinic App.

NOTE: Any new patient created within the Clinic App will only be able to use a CanarE device and will not have access to a Canary account until they are enrolled for a CTE.

2. Complete the required entry fields for the new patient, verify the information is correct, and click **Submit**:

- First and last name
- Middle initial (optional)
- Date of birth
- Height
- Phone
- Email



New CanarE Patient

CanarE patient account ⓘ

First Name * Last Name *

Middle Initial Sex * DOB *

Phone (XXX) XXX-XXXX * Email *

Height * Feet / Inches

Select feet Select inches

3.2.1. Editing Patient Information in the Clinic App

Only a new CanarE patient created within the Clinic App, as described in in Section 3.2, can be edited as needed.



NOTE: If the patient already has a Canary account (created following the CTE with CHIRP System IFUs (K01-CTE-300004 and K01-HBS-300003) or enrolled as described in Section 3.2.2), you will not be able to edit the patient's information within the Clinic App. See CTE with CHIRP System IFUs (K01-CTE-300004 and K01-HBS-300003) for instructions on editing patient account information.

To edit a CanarE patient's information:

1. Select the patient's name and click the **Edit** button.

NOTE: The **Edit** button will only display for CanarE patients who do not have a Canary patient account.

2. Edit the displayed entry fields as desired and click **Submit**.

NOTE: The screen images contain fictitious information as an example only.



3.2.2. Enrolling a Canary Patient in the Clinic App

This section contains instructions for enrolling a CanarE patient for a Canary patient account in the Clinic App for a patient anticipated to receive a CTE implant as a part of their TKA procedure. A Canary patient account can be created from the Physician Dashboard following the CTE with CHIRP System IFU (K01-CTE-300004 and K01-HBS-300003). Alternatively, follow the steps below to enroll a patient for a Canary account:

1. Select a CanarE patient or create a new CanarE patient.
2. Click the **Edit** button. Verify the patient information is correct.
3. Click **Enroll for CTE**.

NOTE: Ensure the patient has access to the email address entered as it is required for them to create their patient account.

4. Verify the patient has Wi-Fi at their home, and then click **Yes** on the pop-up screen.

NOTE: Patients who do not have Wi-Fi at home cannot receive a Canary implant. Select **No** on the pop-up screen and inform the patient that Wi-Fi is required to receive a Canary implant.

? CTE Enrollment

Does the patient have a Wi-Fi network at home?

5. Complete the required entry fields for the new Canary patient.

- Implant Location (left or right knee)
- Time Zone of their home
- Surgery date*
- Surgery time*

***NOTE:** If the surgery date and time are not scheduled or are unknown, enter a future date. This may be edited later from the Physician Dashboard (see CTE with CHIRP System IFU K01-CTE-300004).

6. Verify the information entered is correct and click **Submit**.

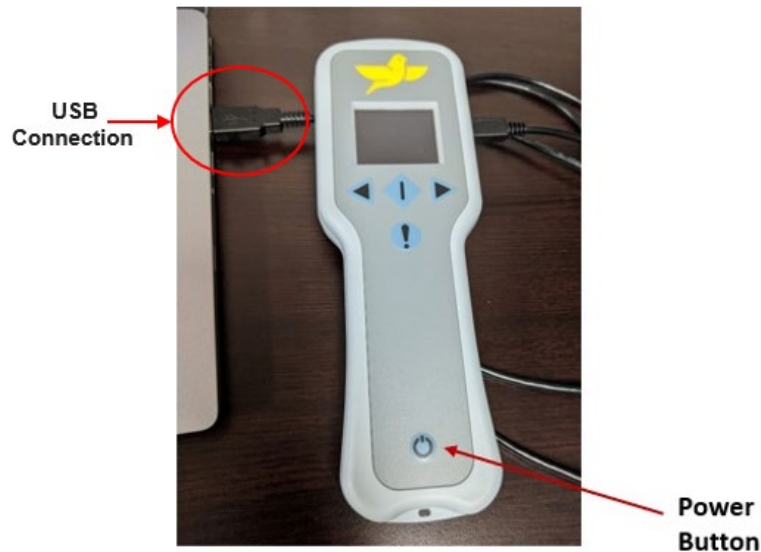
CanarE patient account ⓘ

First Name *		Last Name *	
<input type="text" value="Training"/>		<input type="text" value="Trainer"/>	
Middle Initial	Sex *	DOB *	
<input type="text" value="Enter initial"/>	<input type="text" value="M"/>	<input type="text" value="2/8/1979"/>	
Phone (XXX) XXX-XXXX *		Email *	
<input type="text" value="1112223333"/>		<input type="text" value="trainertest@canarymedicaltest.com"/>	
Height * Feet / Inches			
<input type="text" value="5"/>	<input type="text" value="11"/>		
Implant Location		Patient's Time Zone	
<input type="text" value="Left Knee"/>		<input type="text" value="Pacific Standard Time"/>	
Surgery Date *		Surgery Time *	
<input type="text" value="9/22/2022"/>		<input type="text" value="09"/>	<input type="text" value="00"/> <input type="text" value="AM"/>
<input type="button" value="Cancel"/>		<input type="button" value="Submit"/>	



3.3. Send Test Plan to the Clinic Base Station

1. Ensure the Clinic Base Station is connected to the Laptop with the USB cable and powered on.



2. Select the **patient, CTE or CanarE, Left or Right Knee**, and **Test Plan** to be performed (**Save** Test Plan if modified).
 1. If a CanarE is selected, select the CanarE to be used by serial number (found on the CanarE label on the back on the device).

NOTE: Only one (1) CTE or CanarE device can be selected at a time for data collection.
3. Verify that the patient information, CTE Implant or CanarE device, location, and desired Test Plan are correct.
4. Click the **Send Test Plan to Base Station** button.

3.3.1. Send Test Plan to Base Station: Patient with CTE Implant

canary Patients Test Plans frodo.baggins@canarymedicaltest.com 100% Log Out

Curt Canary Close Patient

DOB: Jun 30, 1975 Date of Surgery: Jul 8, 2022 Primary Physician

Saved Test Plans
 1. You may select and modify any test plan below or create a new test plan on the right.
 STANDARD PLANS (1)
 Default
 MY PLANS (20)
 10 sec walking
 Gait LWRAUP
 Gait RU

Test Options
 2. Select tests from the list below to add them to your test plan.
 TESTS
 Level Walking
 Walking Up Stairs
 Walking Down Stairs
 ROM - Active Prone
 ROM - Passive Prone
 Timed Up and Go

Test Plan
 3. Enter the duration of data collection for test in seconds. Drag and drop tests to reorder them.
 TEST SECS DRAG
 1. Level Walking 10
 2. Level Walking 10
 Test Plan Name: 10 sec walking
 Save Plan
 Total time: 20 (Max 180)

Send Test Plan
 Select device: CTE CanarE
 Select patient's knee: Right Knee
 10 sec walking test plan is ready to be sent.
 Send Test Plan to Base Station

3.3.2. Send Test Plan to Base Station: Patient with CanarE

canary Patients Test Plans frodo.baggins@canarymedicaltest.com 100% Log Out

Curt Canary Close Patient

DOB: Jul 1, 1975 Date of Surgery: Jul 8, 2022 Primary Physician

Saved Test Plans
 1. You may select and modify any test plan below or create a new test plan on the right.
 STANDARD PLANS (1)
 Default
 MY PLANS (20)
 10 sec walking
 Gait LWRAUP
 Gait RU


Test Options
 2. Select tests from the list below to add them to your test plan.
 TESTS
 Level Walking
 Walking Up Stairs
 Walking Down Stairs
 ROM - Active Prone
 ROM - Passive Prone
 Timed Up and Go

Test Plan
 3. Enter the duration of data collection for test in seconds. Drag and drop tests to reorder them.
 TEST SECS DRAG
 1. Level Walking 10
 2. Level Walking 10
 Test Plan Name: 10 sec walking
 Save Plan
 Total time: 20 (Max 180)

Send Test Plan
 Select device: CTE CanarE
 Select patient's knee: Right Knee
 Select a CanarE for This Session: 1435
 10 sec walking test plan is ready to be sent.
 Send Test Plan to Base Station

5. Verify that the Test Plan downloaded successfully and then click **OK**.



 **Test Plan Downloaded**

The test plan **Default** has been downloaded to the base station.

Disconnect the base station to run the test plan, then click Close below.

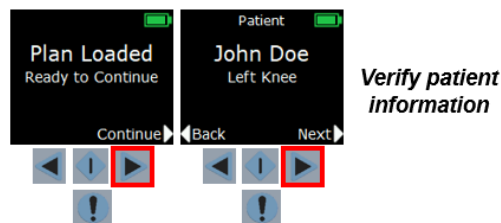
[Close](#)



4. Test Execution

4.1. Beginning a Test Plan with the Clinic Base Station

1. After downloading the Test Plan, **disconnect the Clinic Base Station** from the Laptop to run the test plan with the patient. The Clinic Base Station will automatically reset and power on.
2. The Clinic Base Station screen display Plan Loaded. Press the **Right** toggle button to continue.
3. Verify that the patient and device information are correct.



4. Press the **Left** and **Right** Toggle Buttons to navigate to the desired test the patient will perform.
5. Press the **Select** button to choose the desired test.
6. Provide instructions to the patient prior to beginning each test.
7. When the patient is ready, verify that the Clinic Base Station is within six (6) feet of the patient's CTE or CanarE device to ensure connection.

NOTE: Remove any objects between the Clinic Base Station and the patient's CTE or CanarE device that may interfere with the connection.

8. Press the **Right** Toggle Button to connect to the patient's CTE Implant or CanarE device.

4.2. Level Walking Test

1. Instruct the patient to walk over a flat, level surface in one straight direction in a steady gait while the CTE or CanarE device collects their data.

NOTE: Do NOT instruct the patient to walk in one direction and then turn around and walk back during the data collection period. The change in gait patterns will affect test result data.

2. Select the **Level Walk Test** on the Clinic Base Station.
3. Verify that the patient is ready.

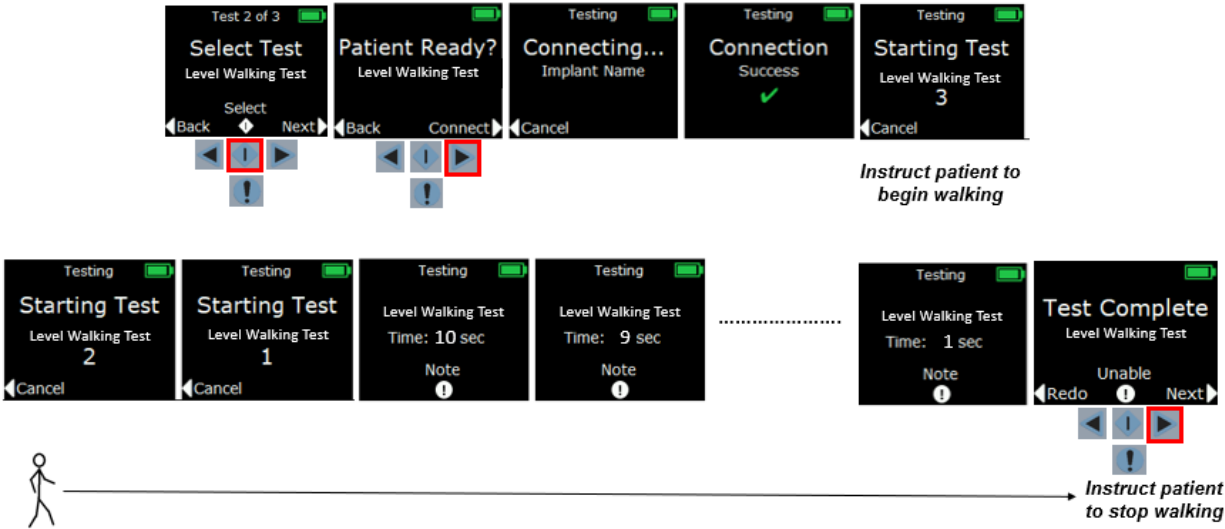
- 4. Press the right Toggle Button to connect to the patient’s CTE Implant or CanarE device.
- 5. Once the Clinic Base Station begins the countdown, instruct the patient to begin walking. This will ensure that the patient is walking in a steady gait during data collection.

NOTE: If the patient begins walking from a standing position when data collection begins, the difference in the gait pattern will affect test result data.

- 6. The data collection should finish before the patient stops the Level Walk Test. This will ensure that the patient is walking in a steady gait throughout the data collection period.

NOTE: If the patient stops walking before completing the data collection, the difference in gait pattern will affect test result data.

- 7. Select **Next** on the Test Complete screen



4.3. Stair Climb Test

- 1. Instruct the patient on the SCT. Ascending or descending stairs while the CTE or CanarE device collects the patient’s kinematic data must be done one at a time according to the respective test selected in the Test Plan.

NOTE: Do NOT instruct the patient to ascend, turn around, and then descend the stairs during the data collection period. The change in gait patterns will affect test result data.

NOTE: The SCT should be completed with a minimum of four (4) stairs.

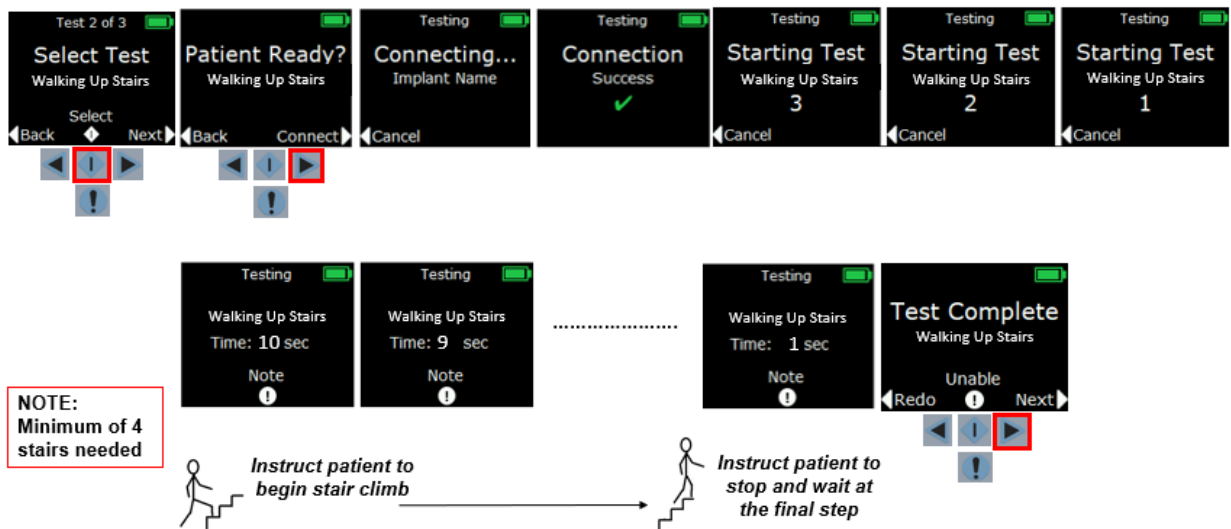
- 2. Select the Walking Up Stairs or Walking Down Stairs test on the Clinic Base Station and ensure the patient is ready.



3. Press the right Toggle Button to connect to the patient's CTE Implant or CanarE device.
4. The Clinic Base Station begins the countdown.
5. Inform the patient to begin ascending or descending the stairs when the data collection starts.
6. The data collection will finish during or after the patient finishes the SCT. If the patient finishes the SCT while data is still collecting, instruct the patient to remain still while the remaining data collection time finishes.

NOTE: If the patient finishes ascending or descending stairs before the data collection stops and they continue to move, the difference in gait pattern may affect test result data.

7. Press **Next** with the right Toggle Button if the patient completed the test and is ready to perform the next test in the Test Plan.

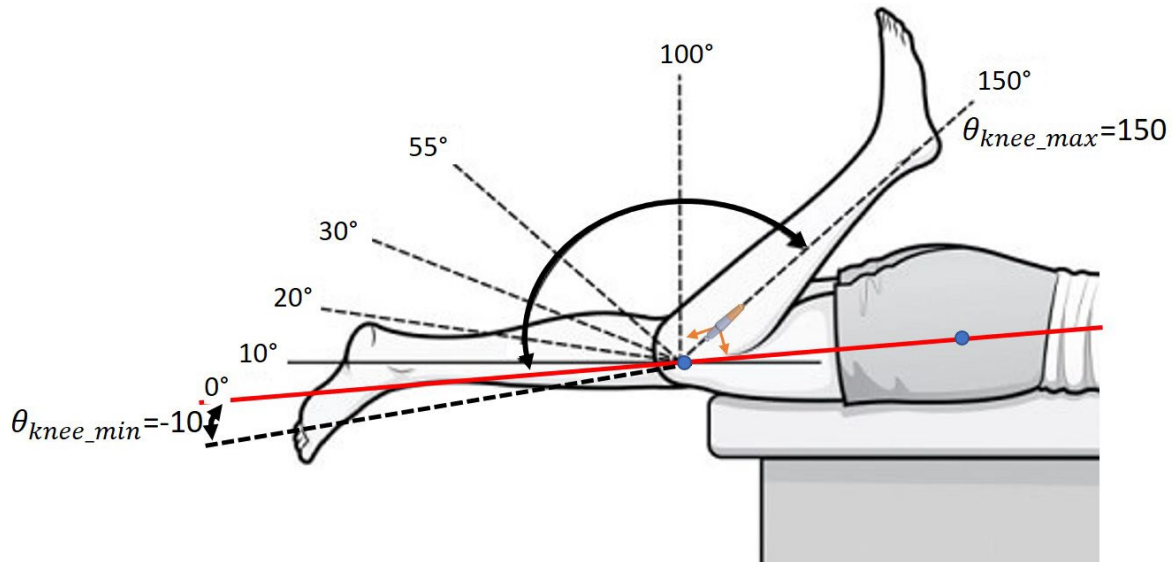


4.4. Prone ROM Test

1. Instruct the patient to lay in prone position on an exam table. The patient's knee should slightly be off the edge of the table to allow full extension.

NOTE: The ROM test with the Clinic Base Station System is performed in the prone position to limit femur motion while collecting data because the CTE or CanarE device can only collect data from the patient's tibia motion.

NOTE: If the patient has pain in this position, they may position their knee on the table. This may result in a slightly reduced ROM.



2. Verify that the patient's hip is not raised during testing which may result in unwanted femur motion.

TIP: Instruct the patient to keep their hands by their side or under their head and their hip against the table while performing the Prone ROM test.

- a. For an Active ROM test, instruct the patient to only move their tibia during testing and to limit their hip and femur motion.
- b. For a Passive ROM test, be sure to limit the patient's femur and hip movement while guiding the flexion-extension movement of the patient's knee.

NOTE: Femur and/or hip movement during ROM testing may affect test result data.

3. Instruct the patient to:
 - a. For a Prone Active ROM test, flex and extend their knee to the maximum extent possible.
 - b. For a Prone Passive ROM test, relax while you guide the flexion-extension movement of their knee to the end of the ROM.
4. ONLY one (1) ROM flexion-extension cycle should be performed while the CTE or CanarE device collects their data.

NOTE: Multiple ROM flexion-extension cycles may affect test result data.

5. Select the Prone ROM Active or Prone ROM Passive Test in the Clinic Base Station.
6. Verify that the patient is ready.
7. Press the right Toggle Button on the Clinic Base Station to connect to the patient's CTE Implant or CanarE device.
8. Wait for the data collection to begin before starting the ROM movement. This allows the CTE or CanarE device to collect the starting position of the patient's tibia.

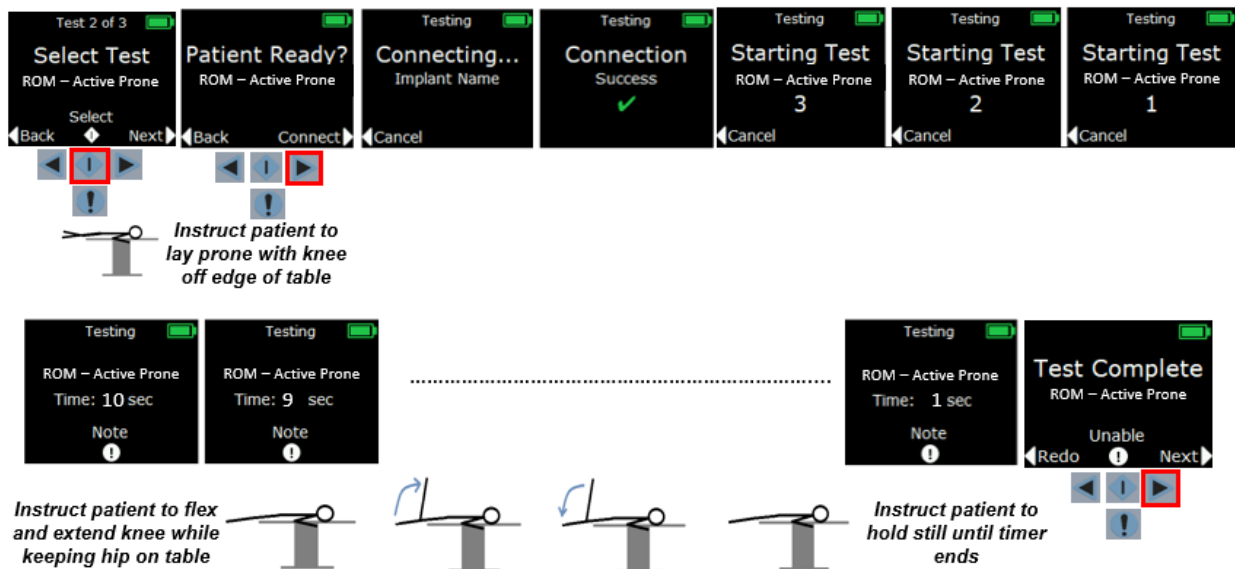
- Instruct the patient to begin the ROM test motion (active) or manipulate the patient's knee (passive) to perform the Prone ROM test.

NOTE: If the patient's leg begins the ROM test motion before the data collection starts, test result data may be affected.

- The patient should finish the ROM test motion before the data collection finishes. Instruct the patient to remain still while the data collection finishes.

NOTE: If the patient's leg is still in motion after the data collection finishes, test result data may be affected.

- Select **Next** on the **Test Complete** screen.



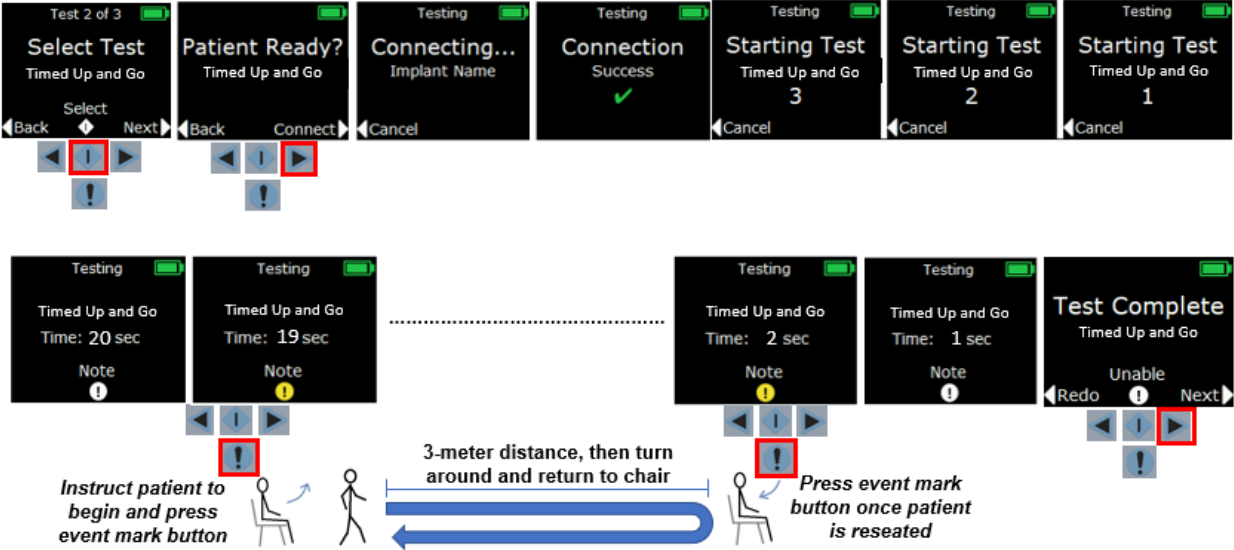
4.5. TUG Test

- Instruct the patient on the TUG test.

NOTE: To perform a TUG Test, generally a patient will sit on a chair with their back against the back of the chair placed at the end of a marked three (3) meters (10 feet) distance. Instruct the patient to stand and walk at a self-selected, comfortable pace past the 3-meter mark, turn around, walk back, and sit down again in the chair without physical assistance, while being timed.

- Select the TUG Test on the Clinic Base Station.
- Verify the patient is ready.
- Press the right Toggle Button on the Clinic Base Station to connect to the patient's CTE Implant or CanarE device.
- Wait for the data collection to begin before starting the TUG Test.

- 6. After data collection begins, instruct the patient to “begin” the test while simultaneously pressing the Event Mark button on the Clinic Base Station. The Event Mark icon on the Clinic Base Station screen will briefly turn yellow. This saves the test start time in the data.
 - 7. When the patient completes the TUG Test, press the Event Mark button. The Event Mark icon on the Clinic Base Station screen will briefly turn. This saves the test stop time in the data.
- NOTE:** The TUG test time is calculated from the first and last Event Mark button presses during the data collection time. Inadvertent Event Mark button presses between the start and stop of the test will not affect test result data.
- 8. **NOTE:** If the Event Mark button presses do not align with the patient starting and stopping the test, test result data may be affected.
 - 9. Select **Next** on the Test Complete screen.



4.6. 360 Degree Turn Test

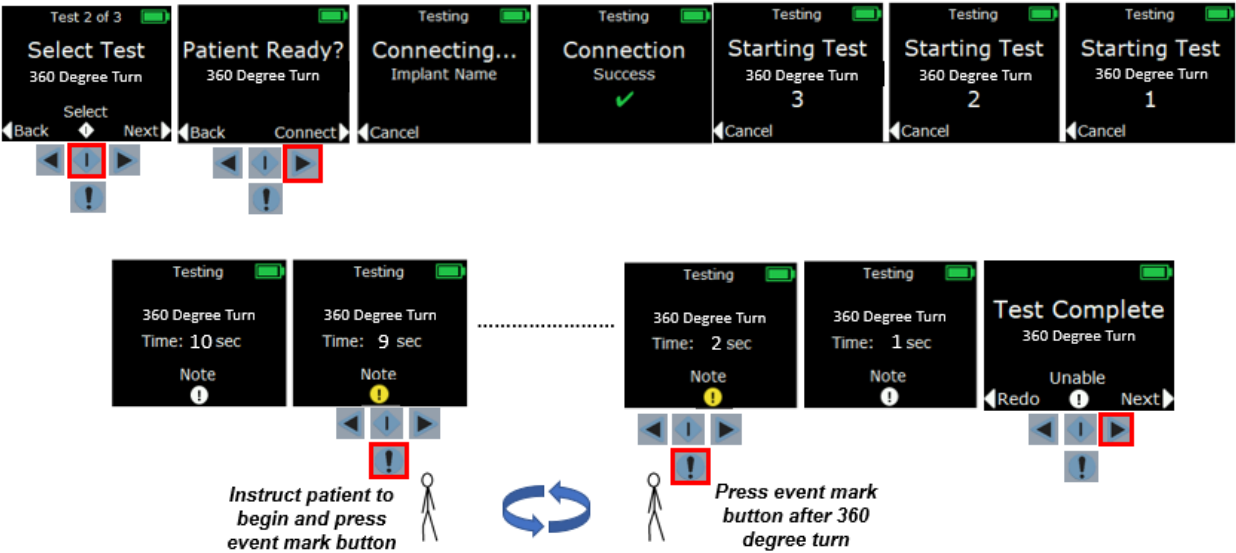
- Instruct the patient on the 360 Degree Turn test.

NOTE: To perform a 360 Degree Turn Test, a patient turns in a complete circle (360 degrees) while the time to complete is recorded.
- Select the 360 Degree Turn Test on the Clinic Base Station.
- Verify that the patient is ready.
- Press the right Toggle Button on the Clinic Base Station to connect to the patient’s CTE Implant or CanarE device.
- The Clinic Base Station begins the countdown.
- Wait for the data collection to begin before starting the 360 Degree Turn Test.
- After data collection begins, instruct the patient to “begin” the test while simultaneously pressing the Event Mark button on the Clinic Base Station.
- When the patient completes the 360 Degree Turn Test, press the Event Mark button on the Clinic Base Station. The button will briefly turn yellow if the Event Mark button was pressed. This saves the stop time of the test.

NOTE: The 360 Degree Turn Test Time is calculated from the first and last Event Mark button presses during the data collection time. Inadvertent Event Mark button presses between the start and stop of the test will not affect test result data.

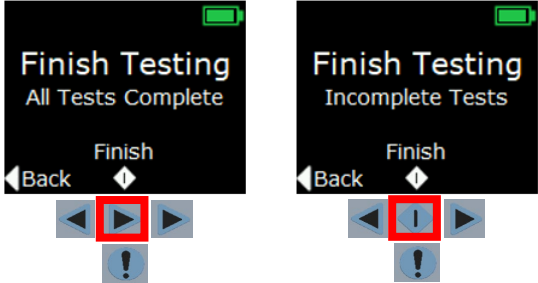
NOTE: If the Event Mark button is pressed and does not align with the patient starting and stopping the test, it may affect test result data.

- Select **Next** on the **Test Complete** screen.



5. Upload Test Results

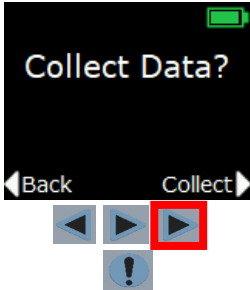
1. Toggle to Finish Testing and push the Select Button.



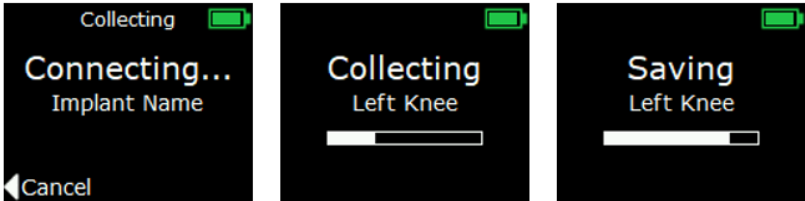
2. The Clinic Base Station will confirm if you would like to collect the testing data from the patient's CTE or CanarE device.
3. Verify that the Clinic Base Station is within six (6) feet of the patient's device.
4. Press the Right Toggle Button to collect the patient's device data.

NOTE: After data has been collected, you cannot go back and perform additional testing. You would need to create a new Test Plan and take the patient through the test process again.

NOTE: Verify that there are no objects between the Clinic Base Station and the patient's CTE or CanarE device that may interrupt the connection.

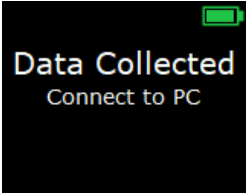


5. The Clinic Base Station will then connect to the CTE or CanarE device and collect and save the data from the device.



6. The Clinic Base Station will confirm the data has been collected successfully. It will store the test data until uploaded to the Clinic App.

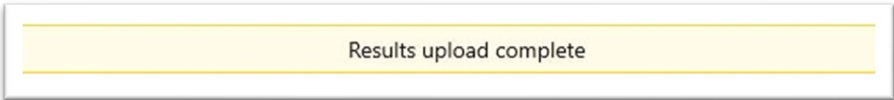
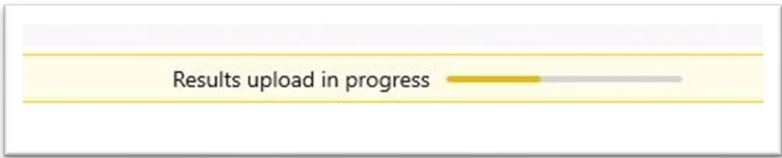




- 7. Return to the Laptop and connect the Clinic Base Station to the Laptop using the supplied USB cable.

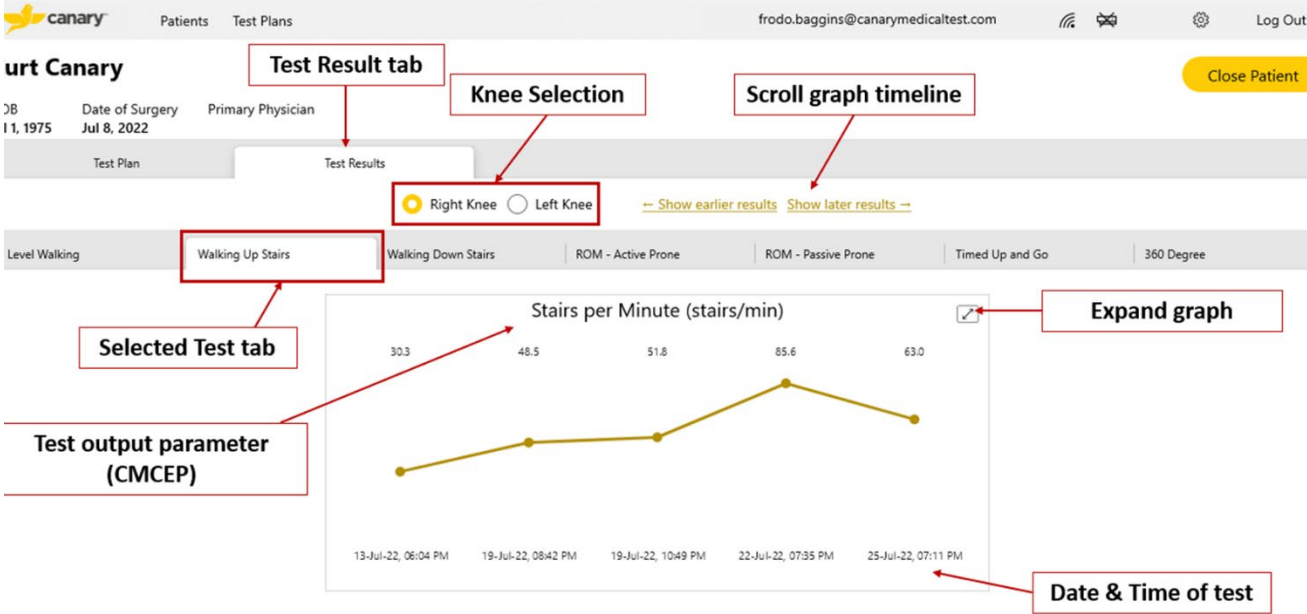
NOTE: Verify that the Clinic Base Station has been powered on when connecting to the Laptop to transfer the test data.

- 8. Log in to the Clinic App. It will automatically upload any saved data from the Clinic Base Station to the Cloud to be processed.



6.Reviewing Patient Test Results

1. Login to the Clinic App to search and select the desired patient.
2. Select the **Test Results** tab to review the device test data.
3. Select the patient's **Left** or **Right** knee and the relevant **Test Tab** to view the results of the respective tests.





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