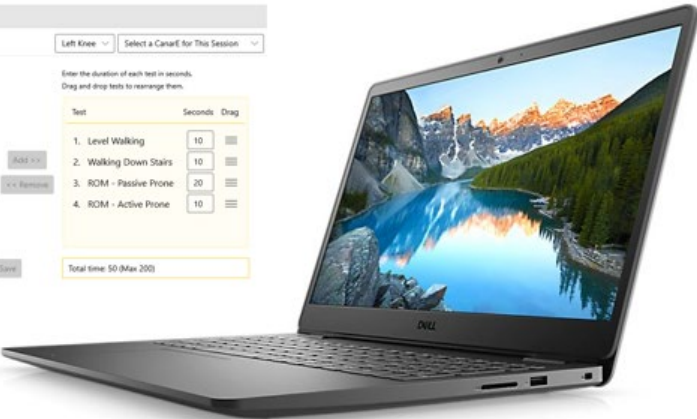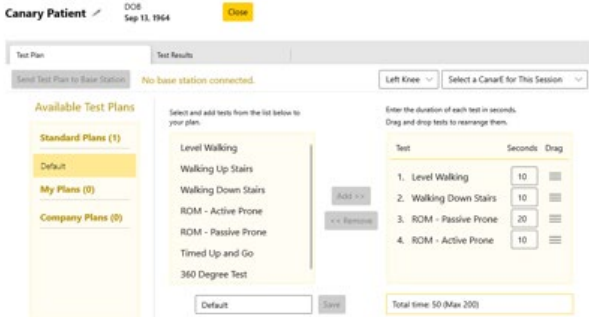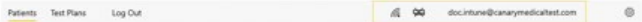# Clinic Base Station System
Instructions for Use

Read this Instructions for Use carefully. If you have additional questions after reading this Instructions for Use, contact Canary Medical.

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How to Contact Canary Medical

Customer Assistance Phone: 1-833-722-6279 or 1-833-7CANARY
Email: support@canarymedical.com
Internet: www.canarymedical.com
Mail:
Canary Medical USA LLC
2710 Loker Ave. West
Suite 350
Carlsbad, CA 92010

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1. Overview

Before using this device, carefully read all instructions for use.

The Clinic Base Station System consists of three (3) subsystems as shown in Figure 1:

- Clinic Base Station (handheld device)
- Clinic Application ("Clinic App")
- Clinic Laptop ("Laptop")

Clinic App

Clinic Laptop

Clinic Base Station
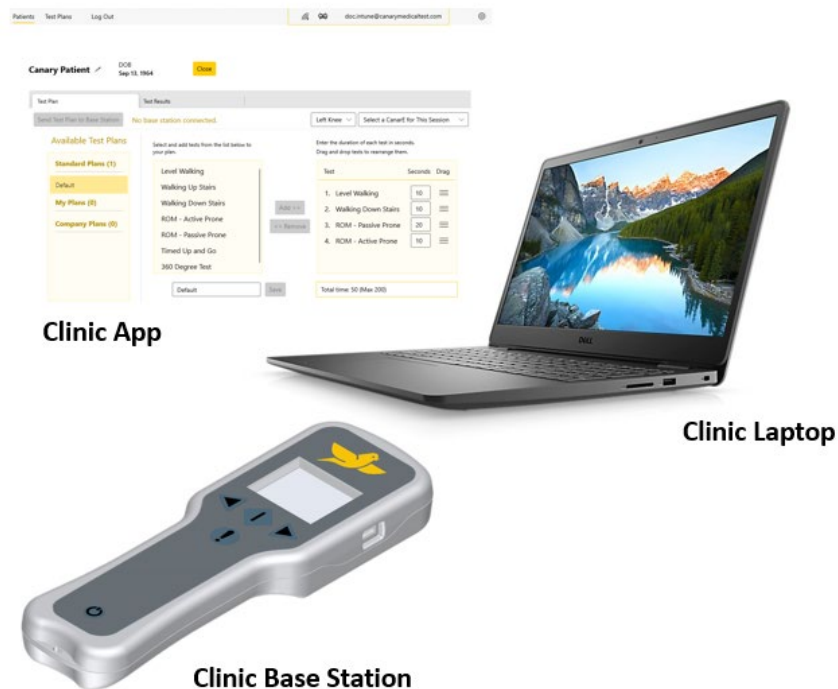
Figure 1: Clinic Base Station System Components

The Clinic Base Station System is intended to be used in conjunction with the Canturio™ Tibial Extension (CTE) with the Canary Health Implanted Reporting Processor (CHIRP™) System and the CanarE™ System specifically with the following subsystems from each of the systems:

- Canturio™ Tibial Extension (CTE)
- Canary Cloud Data Management Platform (CDMP)
- CanarE™ wearable (CanarE)
- Canary Cart

Figure 2 provides a schematic overview of the systems with descriptions of the system components and interfaces.

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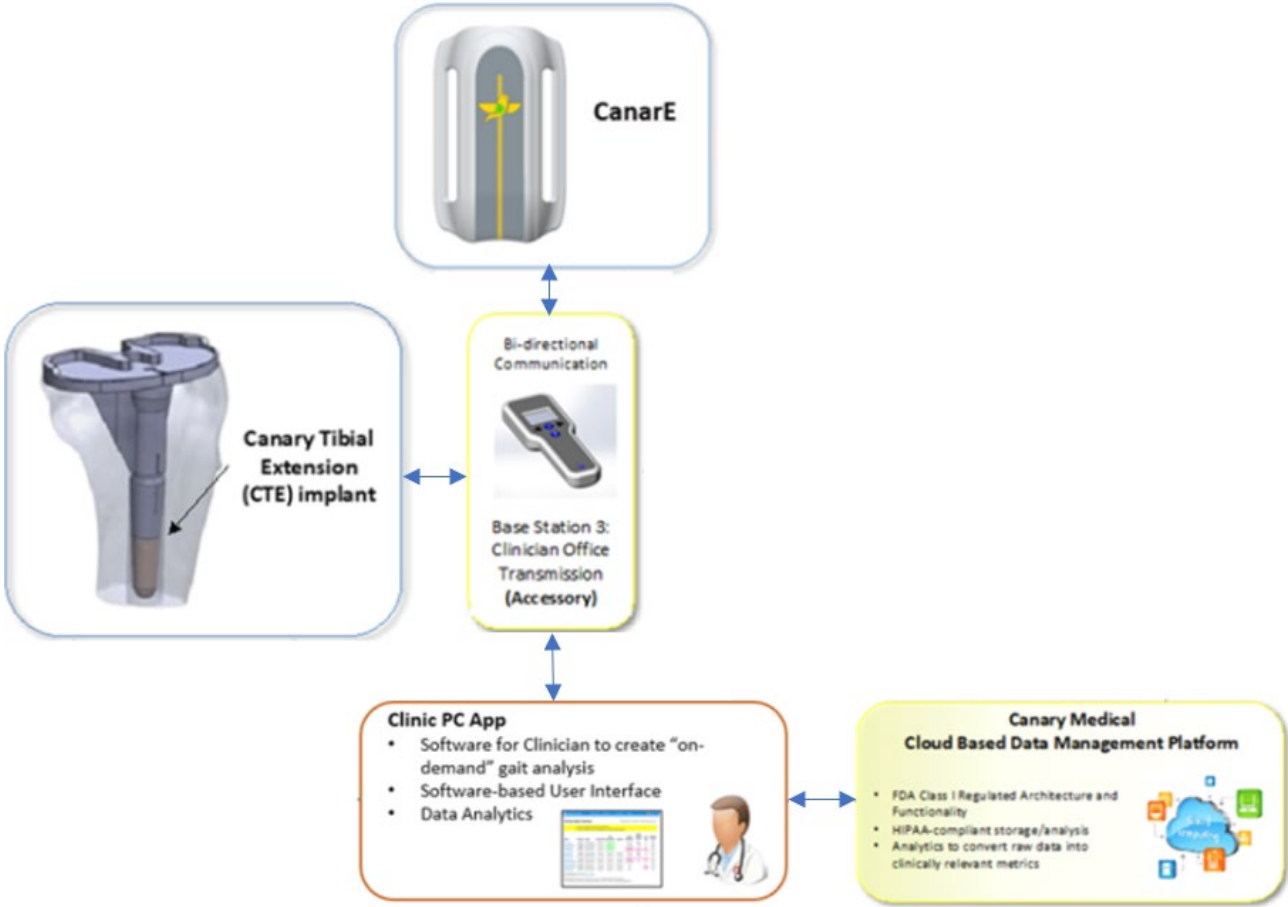
Figure 2: Components and System Interfaces

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2. References

Table 1. Reference Documents

Reference	Title
K01-CTE-300004	CTE with CHIRP System – Physician IFU
K01-HBS-300003	CTE with CHIRP System – Patient IFU
K03-CNE-300005	CanarE System – IFU
K03-CRT-800000	Clinic Cart Assembly Instructions

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3. Terms and Definitions

Table 2: Terms and Definitions

Term	Definition
Base Station	Device used to communicate and collect data from the CTE Implant or CanarE device.
CanarE™	An external wearable device that provides objective kinematic data to assist the clinician before or after a patient's TKA surgical procedure.
CHIRP™	Canary Health Implanted Reporting Processor.
CDMP ("Cloud")	Canary Medical Cloud Based Data Management Platform. The Cloud is a software environment that collects information from a variety of data sources. The information is then stored in a secure encrypted database for retrieval and processing. The Cloud also contains the CMCEP software module that converts the unprocessed kinematic data from the CTE or CanarE to clinical parameters to be viewed in the Clinic App
CMCEP	Canary Medical Clinic Evaluation Parameters. Parameters that summarize the kinematic data collected from a patient's CTE implant or CanarE device for a selected test. The parameters are calculated in the Cloud and displayed in the Clinic App for physicians to review.
CTE	Canturio™ Tibial Extension
EM	Electromagnetic
ESD	Electrostatic Discharge
FW	Firmware
HCP	Health Care Professional
IFU	Instructions for Use
IMU	Inertial Measurement Unit
ISM	Industrial, Scientific and Medical
PC	Personal Computer
ROM	Range of Motion
RTU	Ready to Use
TKA	Total Knee Arthroplasty
USB	Universal Serial Bus

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4. Intended Use

The Clinic Base Station System is intended to provide objective kinematic data on a patient's knee function before or after total knee arthroplasty (TKA) and is intended to be used as an accessory to the Canary Tibial Extension (CTE) with Canary Health Implantable Reporting Processor (CHIRP) System in order to capture kinematic data as directed by a Health Care Professional (HCP) from a patient's CTE or CanarE. The kinematic data produced by the Clinic Base Station System is intended as an adjunct to the standard of care as directed by the physician.

5. Contraindications, Warnings, and Precautions

5.1. Contraindications

None known.

5.2. Warnings

WARNING: Use only cables and accessories supplied by Canary Medical. Use of other cables and accessories may result in increased emissions or decreased immunity of the Clinic Base Station System.

WARNING: Plug Clinic Base Stations and accessories into standard 110V-120VAC wall outlets only. Attempting to connect these items to a non-standard electricity source could cause injury or cause damage to the equipment.

WARNING: Do not stack the Base Stations and accessories or use them adjacent to other electrical equipment.

WARNING: Do not immerse the Clinic Base Station or accessories in water. Electric shock could result.

WARNING: Do not use the Clinic Base Station or accessories if they are damaged. Exposure to internal electronics within the device components could result in electric shock.

WARNING: The Clinic Base Station System components should not be tampered or modified in any way. Exposure to internal electronics may result in harm.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth

5.3. Precautions

CAUTION: Verify that the system components are not visibly damaged prior to use. If damage is observed, do not use.

CAUTION: Do not use electrical converters with the Base Stations or accessories. They have not been tested for this application.

CAUTION: Only use cleaning or disinfecting solutions listed within this IFU. Other solutions have not been tested for this application.

CAUTION: Contact your local authorities to determine the proper disposal method of Clinic Base Station Units and accessories as electronics waste or return them to Canary Medical.

CAUTION: Assess patient fall risk relevant to tests available with the Clinic Base Station System prior to performing the selected test(s).

6. Package Contents

The Clinic Base Station System package contains the following items shown in Figure 3:

- Clinic Base Station (handheld device) with:
  - USB Cable
  - Wall plug (power cable)
- Clinic Laptop with:
  - Clinic App installed
  - Charging and power cable

Figure 3: Clinic Base Station System Components

Table 3 lists all the Clinic Base Station System components and their part numbers.

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Table 3: Clinic Base Station System Components

Part Number	Description
43-5570-005-14	Clinic Base Station unit
	Clinic Base Station power and data cable (provided together with Clinic Base Station unit)
43-5570-003-15	Clinic Laptop with the Clinic Application
	Laptop Charger
WARNING: Use only cables and accessories supplied by Canary Medical. Use of other cables and accessories may result in increased emissions or decreased immunity of the Clinic Base Station System.	

NOTE: Connect only items that are specified as part of the device / system. Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards. Furthermore, all configurations shall comply with the requirements for medical electrical systems (see clause 16 of edition 3 of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible for ensuring that the system complies with the requirements for medical electrical systems.

NOTE: Always position equipment so the mains power connection is accessible.

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7. Device Description

The Clinic Base Station System combines physical components, electronics, software, and user interfaces to collect, store, analyze, transmit, and display patient kinematic data for physicians. Table 3 lists all the Clinic Base Station components and their part numbers. All physical components of the Clinic Base Station system are reusable and supplied non-sterile. The cleaning and disinfecting instructions for components can be found in Section 10.3.

The physician will use the Clinic Base Station to initiate a data collection from a CTE Implant or CanarE device while the patient performs a selected test. After testing is complete, the Clinic Base Station retrieves the data collected from the device and transmits the data to the Clinic App. The Clinic App uploads the patient kinematic data to the Cloud to be processed into the Canary Medical Clinic Evaluation Parameters (CMCEP) for review.

7.1. The Clinic Laptop and Application

NOTE: Use of the Clinic Base Station System in the clinical environment requires internet connectivity to the Clinic Laptop to enable communication between the Clinic App and the Canary Cloud.

Authorized users can log into the Clinic App with their username and password to view associated patient information. The authorized user can also create, save, or modify a test plan for a selected patient. Using a USB connection, the desired test plan, patient selected, and respective CTE Implant or CanarE device can be transmitted to the Clinic Base Station for clinic evaluation.

After clinical evaluation, the Clinic App uploads data from the Clinic Base Station device, via a USB connection, to an external Cloud database for data processing and analysis. CMCEPs are processed and reported from the patient's CTE Implant or CanarE device. CMCEPs are displayed in the Clinic App for a selected patient for review.

7.2. The Clinic Base Station Unit

The Clinic Base Station is a subsystem of the Clinic Base Station System that communicates with a CTE Implant or CanarE device. The Clinic Base Station allows the authorized user to perform "on-demand" data collections from a patient's CTE or CanarE device per the specified patient test plan created in the Clinic App. After the test plan has completed, the Clinic Base Station queries the specified CTE Implant or CanarE device to collect data from the device. This data is transferred to the Clinic Laptop and App via a USB connection for analysis and conversion to CMCEP from the Clinic App.

NOTE: The Clinic Base Station can store only one patient's CTE or CanarE test plan per clinic visit.

The Clinic Base Station, intact skin contacting, material consists of polycarbonate and acrylonitrile / butadiene styrene (PC/ABS), Cycoloy, polyester, and flat silicone.

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7.2.1. Operation

The Clinic Base Station System receives test plans, communicates with the CTE Implant or CanarE device, and commands "on-demand" data collection from the device.

The Clinic Base Station System collects, stores, transmits, and processes the kinematic data generated by the CTE Implant or CanarE device.

7.2.2. Service Life

The Clinic Base Station and accessories are intended to last for 3 years and can be replaced should they become non-operational.

7.3. The Canary Medical Cloud Data Management Platform (Cloud) and CMCEP

The Canary Cloud Data Management Platform ("Cloud") is accessed through the Clinic App. The Cloud subsystem is intended to receive and store all healthcare professional and patient data for pre-operation, day of operation, and post-operation activities, including patient kinematic data from the CTE Implant or CanarE device (see Section 9 for information on data security and patient privacy). The patient kinematic data may be used to monitor the patient as an adjunct to the standard of care.

7.4. CTE and CanarE Device Kinematic Data Collection

The CTE Implant and CanarE devices collect raw kinematic data from its internal inertial measurement unit (IMU); the IMU is the same between the CTE Implant and CanarE device. The raw kinematic data collected on the devices are transferred via the Clinic Base Station to the Canary Cloud where it is processed by the CMCEP software module of the Clinic App into parameterized data for presentation to the authorized physician.

7.5. Knee Mobility Assessment Tests

There are seven (7) knee mobility assessment tests that an HCP can select to perform on a patient who has a CTE Implant or is using a CanarE device. These assessment tests include:

- Level Walking
- Stair Climb Test (SCT) Ascending
- Stair Climb Test (SCT) Descending
- Active ROM (Prone position)
- Passive ROM (Prone position)
- Timed Up and Go (TUG)
- 360 Degree Turn

Each test has a specified output parameter(s), referred to as the CMCEP as summarized in Table 4.

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Table 4: Clinic Evaluation Tests and the respective CMCEP reported

Test Plan Tests		Test Report Output Parameters								
Test	Test Name	Walking Speed (m/s)	Cadence (steps / min)	Stride Length (m)	Functional Knee ROM (deg)	Tibia ROM (deg)	Prone Knee ROM (deg)	TUG Time (sec)	360 Turn Time (sec)	Stairs per min (stairs / min)
1	Level Walking	X	X	X	X	X				
2	SCT (Ascending)									X
3	SCT (Descending)									X
4	ROM – Active Prone						X			
5	ROM – Passive Prone						X			
6	TUG							X		
7	360 Degree Turn								X	

The Level Walking test output parameters are defined below in Table 5.

Table 5: Level Walking Test Output Parameters

Parameter	Definition
Walking speed	Mean sagittal plane distance walked per unit of time during level walking (m/s)
Cadence	Mean steps per minute during level walking (steps/min)
Stride Length	Mean distance traveled during a single gait cycle during level walking (m)
Functional Knee ROM	Mean sagittal plane functional knee joint range of motion during level walking (degrees)
Tibia ROM	Mean sagittal plane tibia range of motion with respect to the floor during level walking (degrees)

The remaining test's, summarized in Table 4, respective output parameters, are defined below in Table 6.

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Table 6: Test Output Parameters

Parameters	Definition
Stairs per minute	Mean stairs per minute (stairs/min) when ascending or descending stairs
Passive prone knee ROM	Knee ROM (full extension to maximum flexion) with the HCP assisting the movement in the sagittal plane (degrees)
Active prone knee ROM	Knee ROM (full extension to maximum flexion) under unassisted volitional movement in the sagittal plane (degrees)
TUG time	Total time to complete the timed up and go test
360 turn time	Total time to complete a 360 degree turn in place

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8. Directions for Use

The following information describes how to use the Clinic Base Station System in task order. This information is provided from a user perspective. It is intended to provide directions for HCPs (including surgeons, surgeon's staff, physicians, and nurses) in using the Clinic Base Station System. It is also intended to inform HCPs about their patients' roles when using the system to support patients' understanding of their health care needs.

8.1.   **Getting Started: Clinic Laptop and Clinic App**

1. Remove the Clinic Laptop from its packaging.

2. Verify that the Clinic Laptop is not damaged. If damage is observed, do not use the laptop. Return the laptop to Canary Medical for replacement.

3. After confirming the Laptop is not visually damaged after unpacking, plug the Laptop into power using the supplied power cord to charge the Laptop.

   NOTE: The Laptop may be used while not connected to the power cord if the battery has sufficient charge.

   NOTE: The Laptop may be used with the Clinic Cart for power connection and transportation. Refer to the CanarE System IFU for details.

4. Turn on the Laptop.

5. Verify that the Laptop has established a Wi-Fi internet connection.

   NOTE: To use the Clinic Base Station System, the Laptop requires internet access to connect to the Canary Cloud Data Management Platform.

6. Launch the Canary Clinic App if it does not automatically open.

7. Enter your Canary Username and Password to log in to the Canary Clinic App
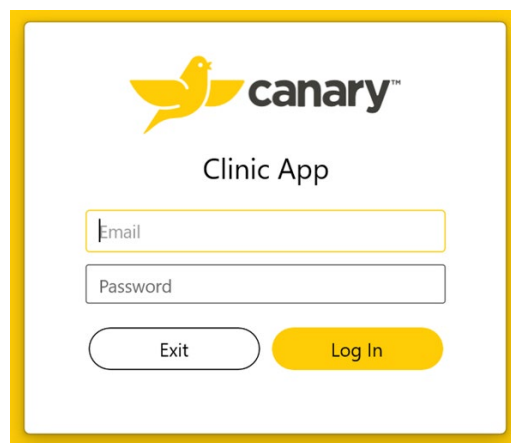
Figure 4: Canary Clinic App Login Screen

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8. The Clinic App displays the Wi-Fi connectivity status, the Clinic Base Station connection status, and the Clinic Base Station charge status if connected as shown in Figure 5.
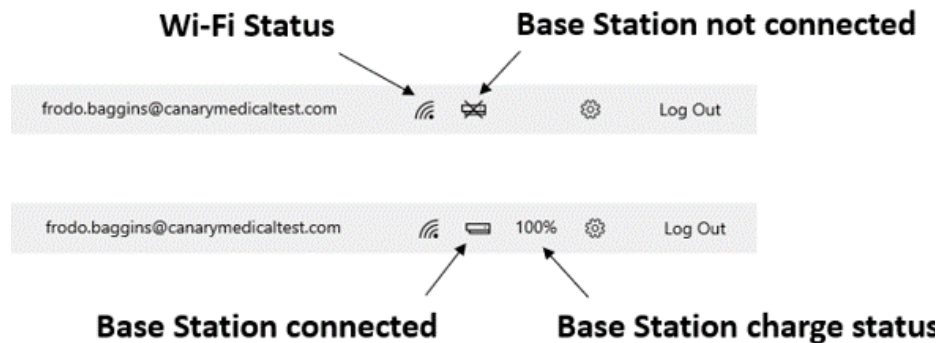
Figure 5: Clinic App Status Symbols. Base Station Not Connected (top);
Base Station Connected and Charge Status (bottom)

8.2. Getting Started: Clinic Base Station

1. Remove the Clinic Base Station and components from its packaging.

2. Verify that the Clinic Base Station and its components are not damaged.

3. If desired and not already connected to the Clinic Base Station, connect the wrist strap ring to the bottom of the Clinic Base Station. Wear the wrist strap while using it to prevent dropping the device.

4. The Clinic Base Station power cord is a USB cable that may be connected to either the wall power adapter or directly to the Laptop to charge it.
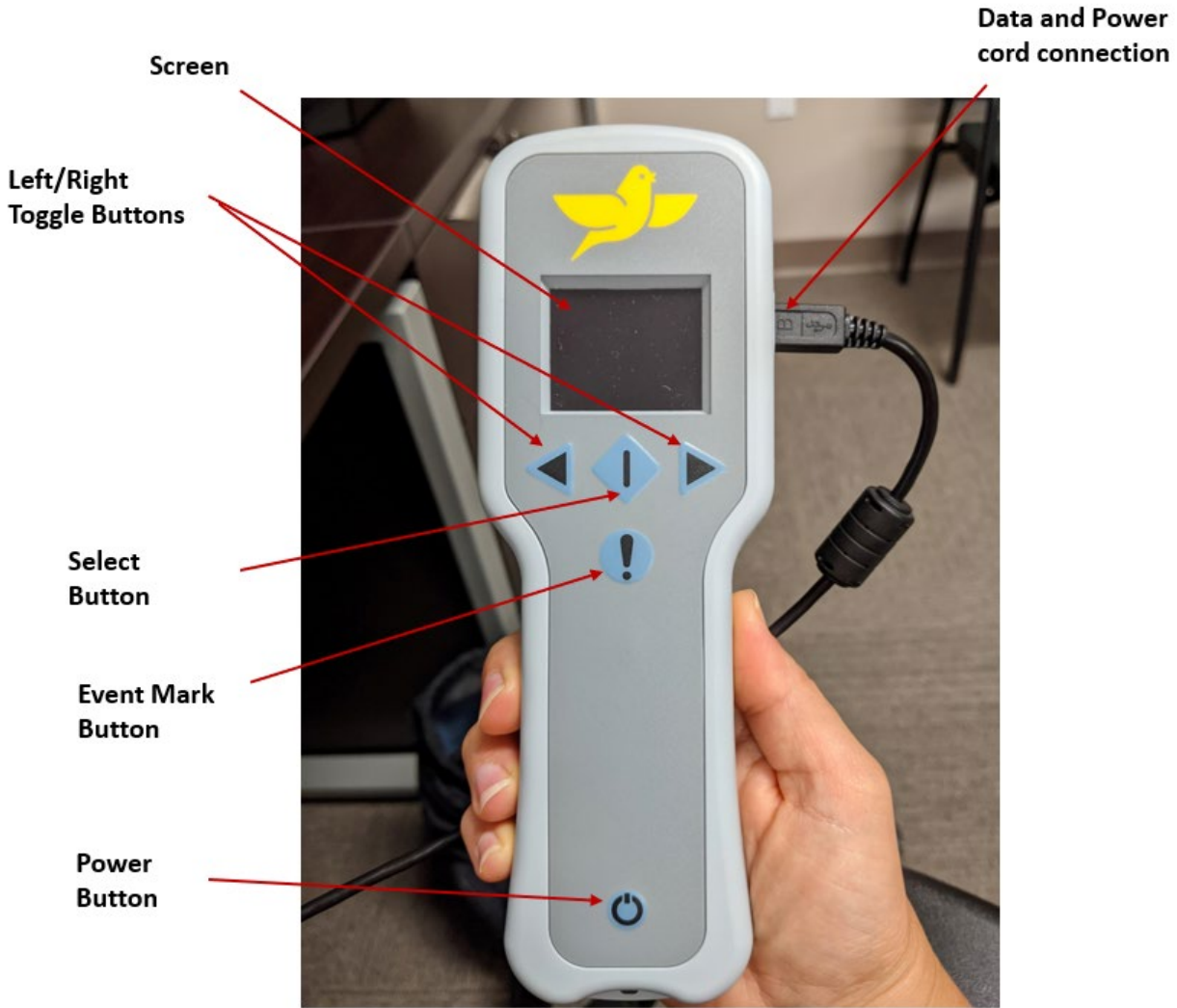
   NOTE: The Clinic Base Station will only operate on battery power if the battery has sufficient charge, and a test plan has been downloaded to it from the Clinic App prior to use.

   NOTE: The Clinic Base Station may be used with the Clinic Cart for connection to the Laptop and power as well as for transporting. Refer to the CanarE System IFU for details.

5. Connect the Clinic Base Station to the Laptop as shown in Figure 6.

   NOTE: Only connect one (1) Clinic Base Station to the Laptop at a time if you are going to send a test plan to the Clinic Base Station

6. Press the Power button (at the bottom of the device) to turn it on. The remaining button layout is also identified in Figure 6.

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Data and Power
cord connection

Screen

Left/Right
Toggle Buttons

Select
Button

Event Mark
Button

Power
Button

USB connection port

Figure 6: Clinic Base Station Connected to the Laptop with a USB Cable Along with a Button Layout

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8.2.1. Clinic Base Station Charge Status

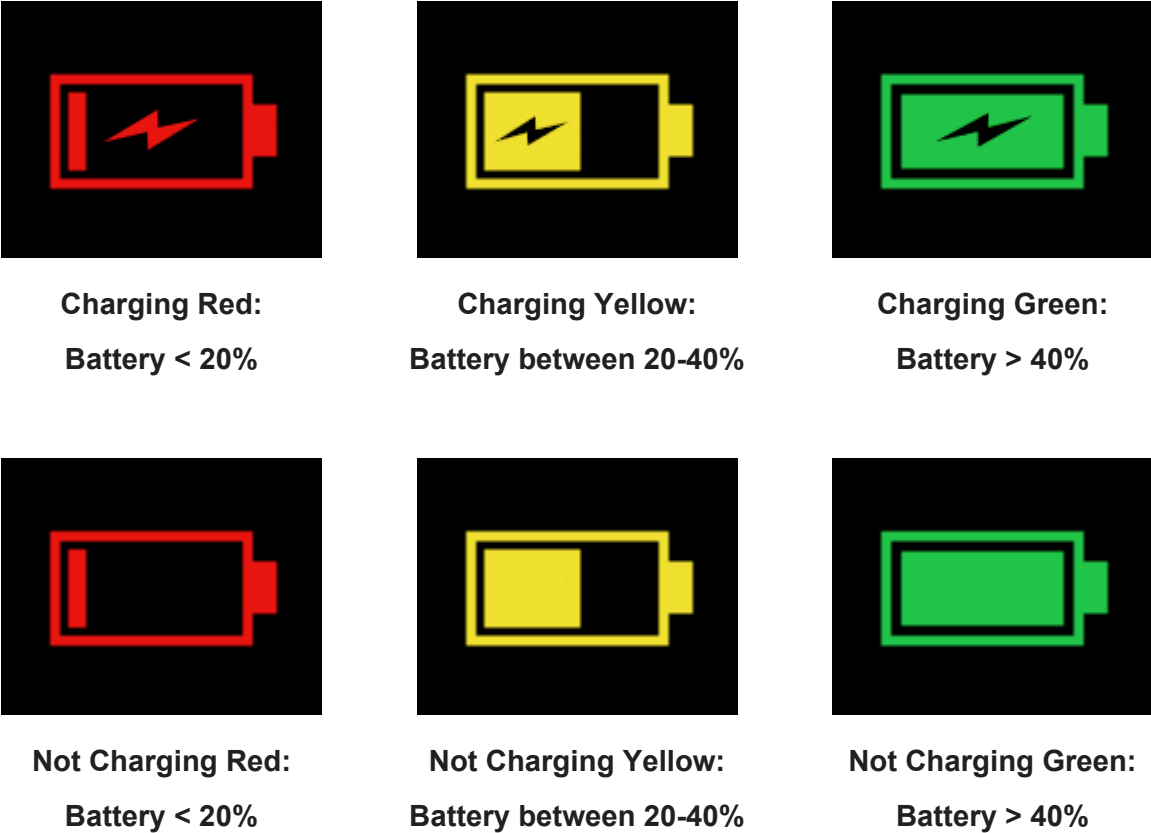The Clinic Base Station charge status is displayed on the screen and is defined in Figure 7.

| **Charging Red:** | **Charging Yellow:** | **Charging Green:** |
| Battery < 20% | Battery between 20-40% | Battery > 40% |

| **Not Charging Red:** | **Not Charging Yellow:** | **Not Charging Green:** |
| Battery < 20% | Battery between 20-40% | Battery > 40% |

Figure 7: Clinic Base Station Battery Charge Status Screens

8.3. Creating a Test Plan in the Clinic App

After logging into the Clinic App as described in Section 8.1, you can create a test plan for patient test evaluations.

1. Click the **Test Plans** tab as shown in Figure 8.

2. The Canary Default Test Plan will be displayed as an option to select. The Default Test Plan includes each test option described in Section 7.5 with a collection time set for each test as shown in Figure 8.
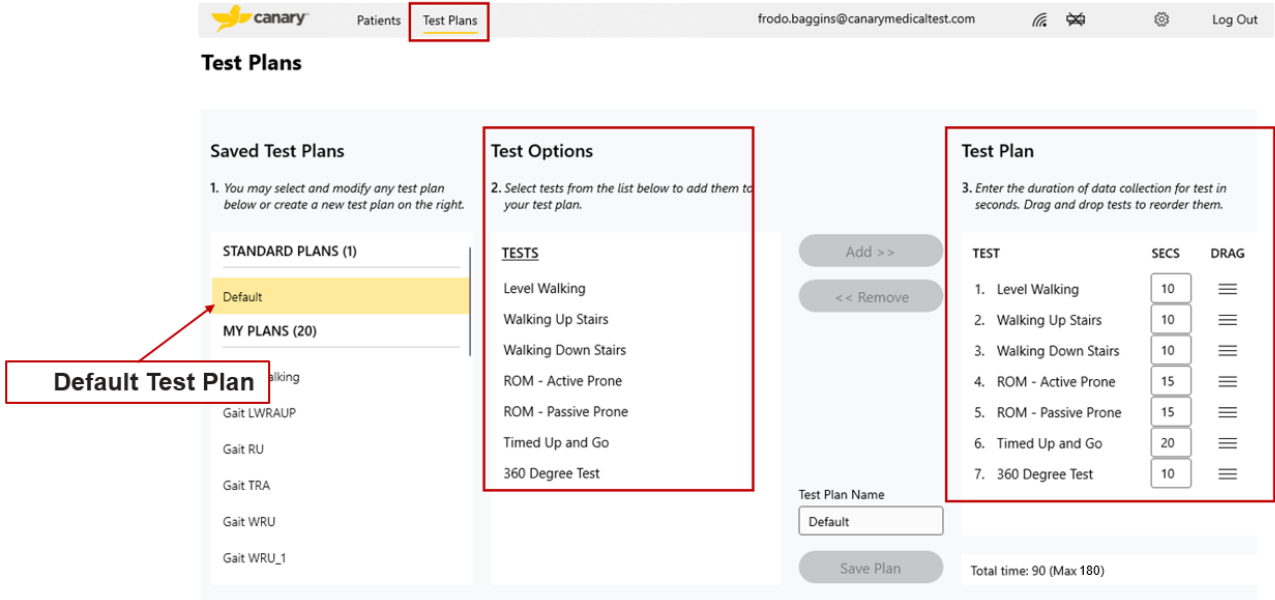
Figure 8: Clinic App Default Test Plan screen

A customized test plan can be created, saved to your Canary account, and then used for any selected patient. To create a customized test plan:

3. Select a test from the Test Options list and then click **Add** to add the tests you would like to perform as shown in Figure 9.

4. Select a test from the Test Plan and then click **Remove** to remove a test from the plan as shown in Figure 9.

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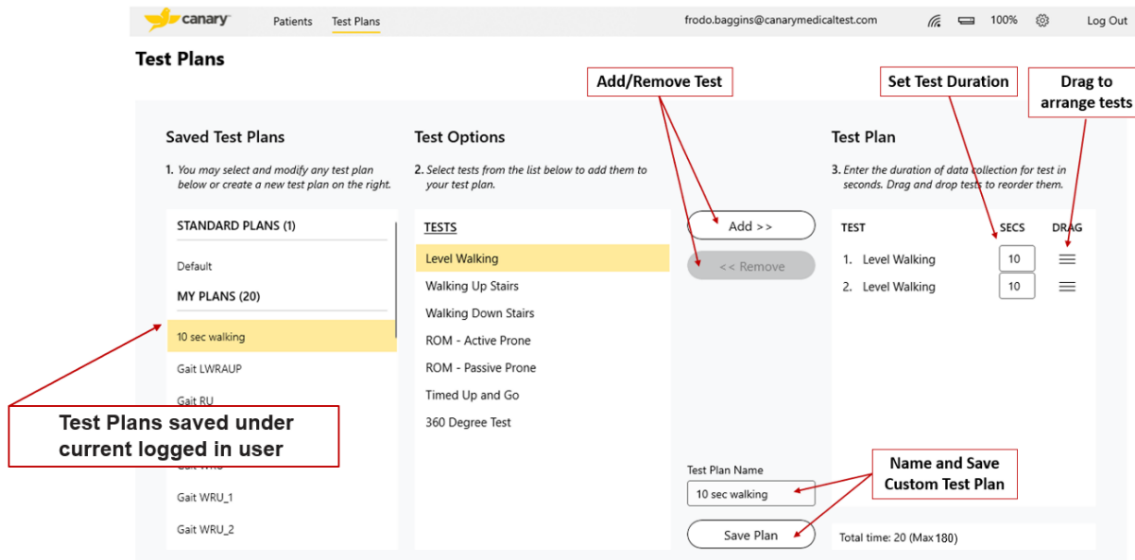
Figure 9: Customize Test Plan

5. 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.

6. Set the test duration time in seconds for each test. 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 as shown in Figure 9.

   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.

7. Enter a name for the customized test plan.

8. Click **Save**. This plan will be saved to your account under the **My Plans** header and can be used for any of your patients as shown in Figure 9.

   NOTE: Other HCPs who create custom test plans within your same clinic account are able to use them for any of your other patients by selecting the Test Plan under the **Company Plans** header as shown in Figure 10.

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Figure 10: Save Custom Test Plan and Total Data Collection Time Screen

8.4. Selecting a Patient in the Clinic App

1. After logging into the Clinic App, by following the directions in Section 8.1, you can search for and select the patient you want for evaluation.

2. Click the **Patients** tab.

3. To search for the patient, 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 as shown in **Figure 11**.

4. 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.

5. If the patient is new, select **Create a New Patient** and then follow the steps in Section 8.5.
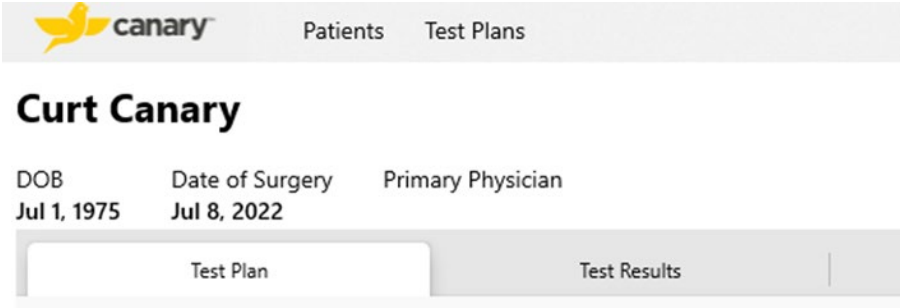
Patient Search

Find an existing patient

cur

Curt Canary

Search and select patient

Figure 11: Search for Existing Patient

6. Verify that the displayed patient information is correct for the desired patient as shown in Figure 12. 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.
   NOTE: The screen images contain fictitious information as an example only.

canary   Patients   Test Plans

Curt Canary

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

Test Plan   Test Results

Figure 12: Patient Information Screen

8.5. Creating a New CanarE Patient in the Clinic App

1. If a patient name does not display in the search results as described in Section 8.4, click the **Create a New CanarE Patient** button shown in Figure 13.

   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 8.5.1 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 (see Section 8.5.1).
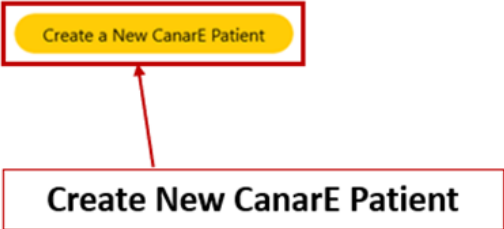
Figure 13: Create a New CanarE Patient Screen

2. Complete the required entry fields for the new patient as shown in Figure 14:

   - First and last name

   - Middle initial (optional)

   - Date of birth

   - Height

   - Phone

   - Email

Figure 14: Clinic App New Patient Screen

3. Verify the entries are correct as this will affect the Cloud's output data.

4. Click **Submit**.

8.5.1. Editing Patient Information in the Clinic App

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Only a new CanarE patient created within the Clinic App, as described in Section 8.5, 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 8.5.2), 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.

2. Click the **Edit** button as shown in Figure 15.

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

3. Edit the displayed entry fields as desired.

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

Figure 15: CanarE Patient Information Edit Button in the Clinic App

4. Click **Submit**. The updated CanarE patient information has now been saved.

### 8.5.2.   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.

3. Verify the patient information is correct.

4. 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.

5. 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 shown in Figure 16and inform the patient that Wi-Fi is required to receive a Canary implant.
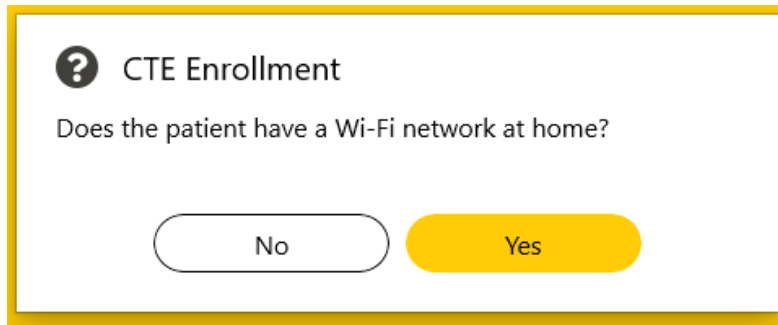
Figure 16: Patient Wi-Fi Verification Screen on the Clinic App

6. Complete the required entry fields for the new Canary patient as shown in Figure 17(the image contains fake information as an example only).

- 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).

7. Verify the information entered is correct.

8. Click **Submit.**

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Figure 17: Enroll a CanarE patient for a Canary Patient Account

9. A pop-up screen will confirm that the patient enrollment was successful. The patient can now create their Canary patient account according to the CTE with CHIRP System IFU (K01-HBS-300003).

> **NOTE:** If enrollment was not successful, verify internet connection is established and retry. If the problem persists, logout of the Clinic App and log back in or restart the Clinic Laptop and retry. If issue continues, contact Canary Medical.

8.6. Performing a Patient Evaluation

This section contains instructions for conducting knee kinematic assessments before or after TKA using the Clinic Base Station System. After selecting a patient or creating a new patient, perform the patient evaluation as follows:

8.6.1. Select Patient's CTE or CanarE Device in the Clinic App

Only one (1) device (CTE or CanarE) can be used at a time collect data while performing a Test Plan with a patient. A Test Plan must be sent to the Clinic Base Station for each evaluation with the patient's CTE or CanarE device selected.

8.6.2. Selecting a Patient's CTE Implant Device

1. If the patient has received a CTE Implant, it will automatically select it and display as shown in Figure 18. If that patient has bilateral implants, click the CTE button and then **Left Knee** or **Right Knee** from the drop-down list.

   NOTE: If the patient has bilateral CTE Implants, only one (1) implant can be selected at a time for data collection.

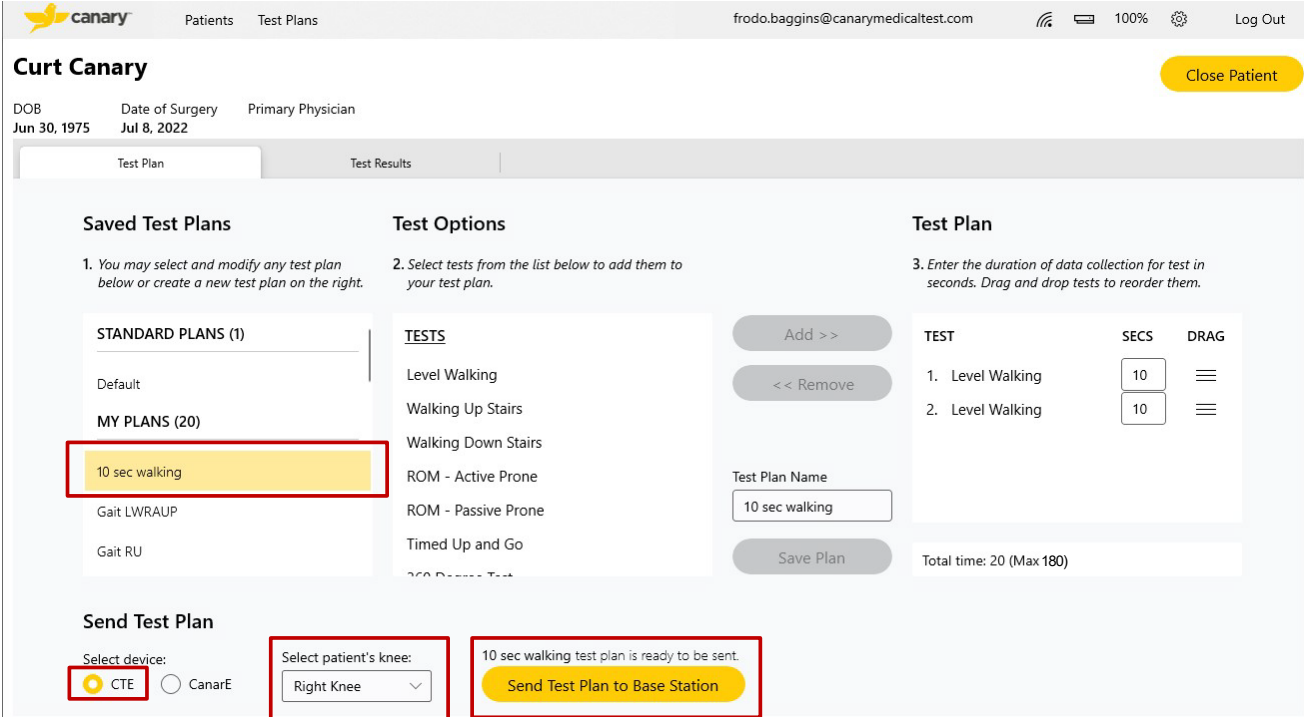   **NOTE**: The screen images contain fictitious information as an example only.

Figure 18: Patient Information Screen with CTE Selected

8.6.3. Selecting the CanarE device

1. Click the **CanarE** button as shown in Figure 19.

2. Select **Left Knee** or **Right Knee** for where the CanarE will be attached.

3. Select the CanarE device ID from the drop-down list, as shown in Figure 20, for the device that will be used.

   NOTE: Only one (1) CanarE device can be selected at a time for data collection.

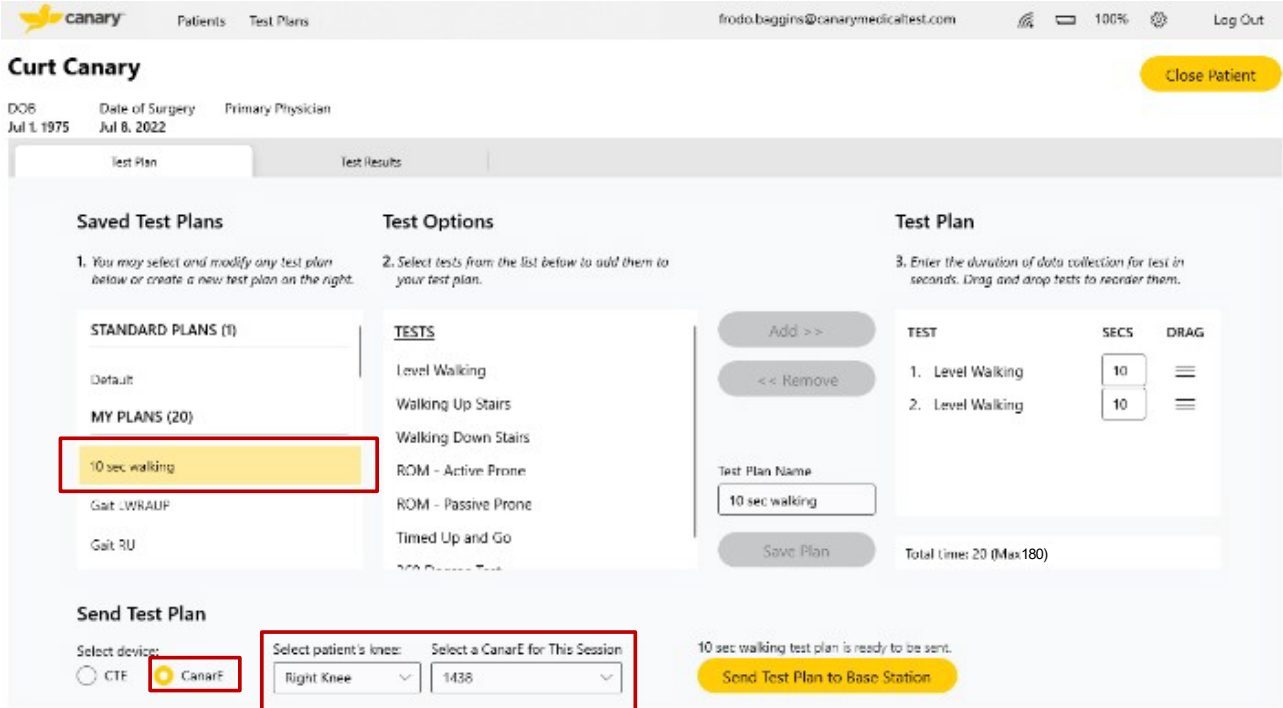   **NOTE**: The screen images contain fictitious information as an example only.

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Figure 19: Selecting a CanarE Device, Its Location, and ID to Be Used for the Selected Patient

4. If the CanarE device is not listed, select **New CanarE** from the drop-down list, and then enter the new CanarE serial number.

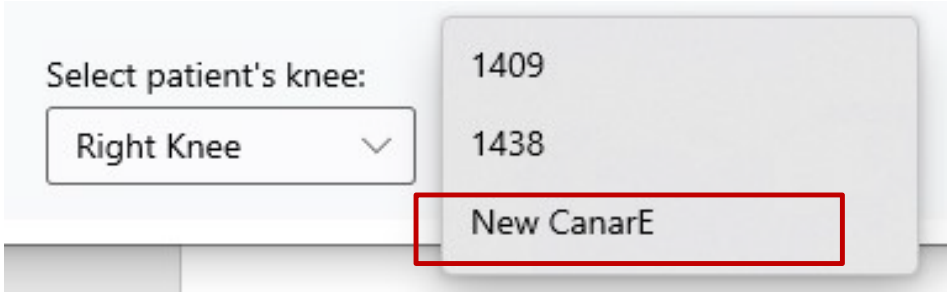   **NOTE**: The screen images contain fictitious information as an example only.

Figure 20: Adding a New CanarE Device

5. Save the new device entry to add it to the list and to your account. The CanarE serial number can be found on the CanarE label as indicated in Figure 21.

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CanarE

canary™

REF **43-5570-007-14**
EDI **43557000714**
SN **123456**
� **2021-12-23**

(01)00860003118344
(21)123456

2AYAJ-
CNE   canarymedical.com/resources/
Distributed by:

ZIMMER
1800 W. Center Street
Warsaw, Indiana 46580 USA

MADE IN CANADA
K03-CNE-300001 Rev. B

Figure 21: CanarE Label Serial Number

8.6.4. Download Patient Test Plan to the Clinic Base Station in the Clinic App

1. Select the patient and device.

2. Select the desired Test Plan to be performed.

   NOTE: Test Plans may be further modified as described in Section 8.3.

3. Click **Save** if any modifications are made.

4. Connect the Clinic Base Station to the Laptop as shown in Figure 22.

5. Press the Power button to turn on the device.
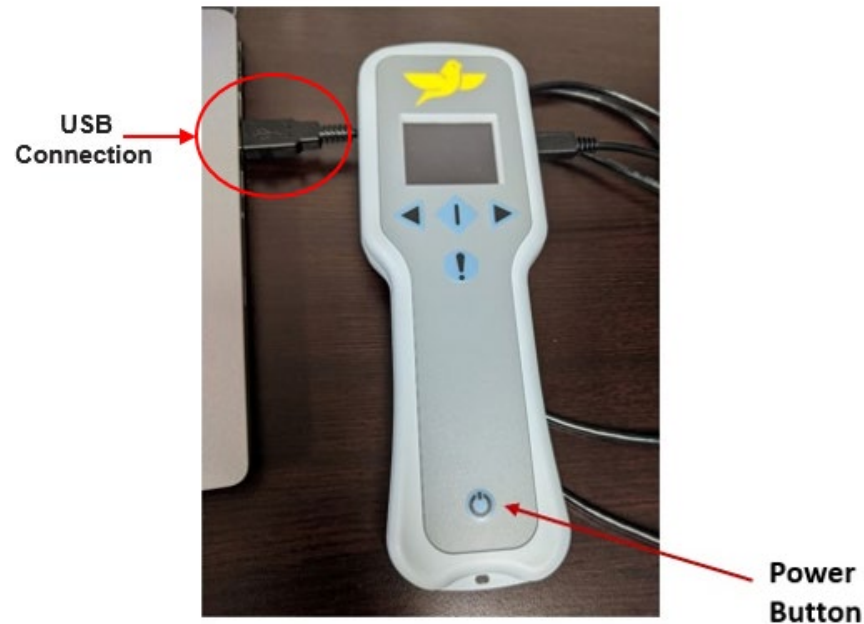
Figure 22: Clinic Base Station Connected to the Laptop via USB

6. Verify that the patient information, CTE Implant or CanarE device, location, and desired Test Plan are correct.

7. Verify that the Clinic Base Station has been charged.

   NOTE: The Clinic Base Station will only operate if the battery has sufficient charge.

   NOTE: Notifications will indicate when information is missing prior to sending the Test Plan.

8. Click the **Send Test Plan to Base Station** button.

9. Verify that the Test Plan downloaded successfully.

10. Click **OK.**
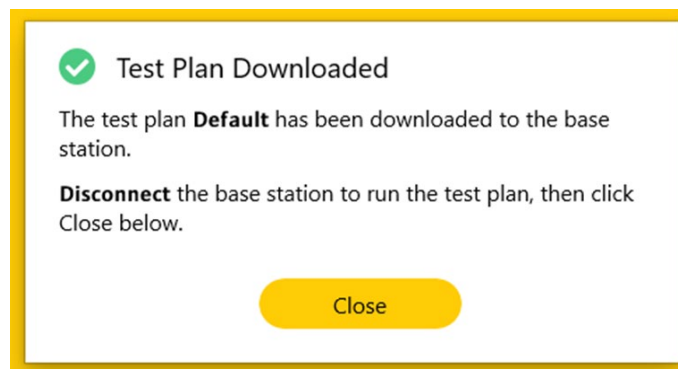
Figure 23: Test Plan Download Status Screen

11. 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. The Canary logo will display on the splash screen as the device powers on.

Figure 24: Clinic Base Station Power on Splash Screen

8.6.5. Beginning a Test Plan with the Clinic Base Station

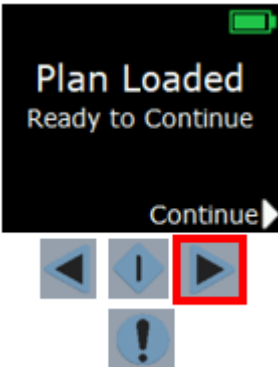1. The Clinic Base Station Plan screen will confirm the Test Plan has been loaded and is ready to continue.

Figure 25: Clinic Base Station Plan Loaded and Ready to Continue Screen

2. Press the right Toggle Button to continue.

3. The Clinic Base Station screen will display the selected patient and CTE Implant or CanarE device location.

Figure 26: Clinic Base Station Patient Screen

4. Verify that the patient and device information are correct.

5. Press the right Toggle Button to continue.

6. Press the left and right Toggle Buttons to navigate to the desired test the patient will perform.
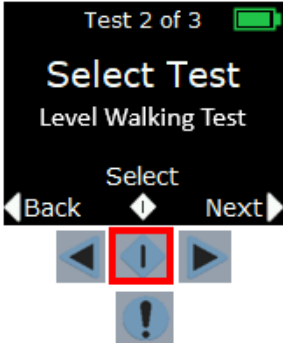
7. Press the **Select** button to choose the desired test.

Figure 27: Clinic Base Station Test Selection Screen

8. Instruct the patient on how to perform the selected test. (See Sections 8.6.6 -8.6.10).

9. 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.

10. Press the right Toggle Button to connect to the patient's CTE Implant or CanarE device. The displays will appear as shown in Figure 28.
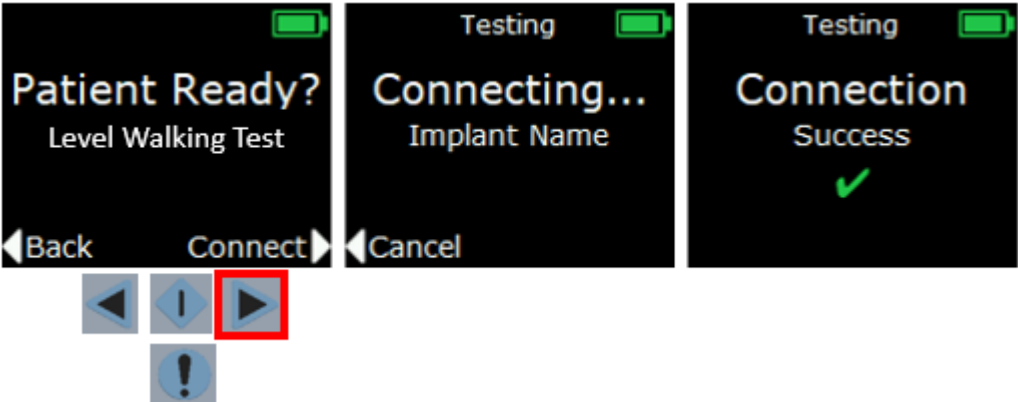

Figure 28: Clinic Base Station Patient Ready and Connecting to CTE or CanarE Screens

11. After the CTE or CanarE device has connected to the Clinic Base Station, it will count down from three (3) seconds to indicate when the data collection will start.
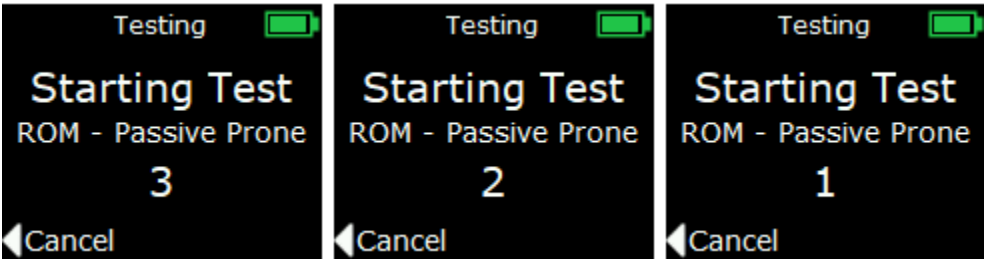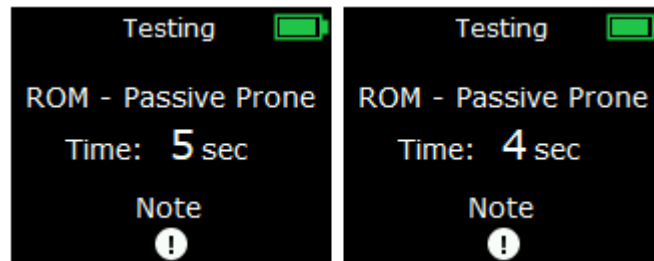

Figure 29: Clinic Base Station Data Collection Starting Screens
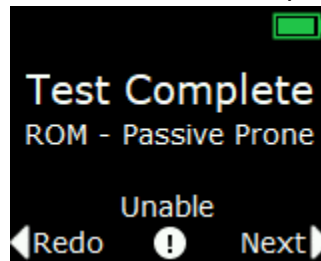
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12. Observe the patient while they perform the test. The Clinic Base Station will start the countdown based on the data collection time set in the Test Plan.

Figure 30: Clinic Base Station Data Collection Countdown Screens

13. After the test completes, the Clinic Base Station displays the **Test Complete** screen.

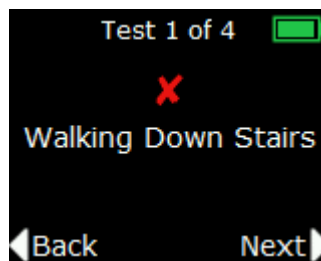*Figure 31: Clinic Base Station Test Complete Screen - ROM*

14. Select the desired option using the **Select** button or the left and right Toggle Buttons.

15. Redo – Press **Redo** with the left Toggle Button if you would like to have the patient repeat the test that was just performed.

    NOTE: If **Redo** is selected, the last collected test data will be processed for review.

    NOTE: The **Redo** option is not available if the maximum data collection time has been reached.

16. Unable – Select **Unable** with the Event Mark button if the patient could not complete the selected test (e.g., pain, fatigue, etc.). The data from this test will not be processed for review. The Test Selection screen on the Clinic Base Station will indicate a red 'X' that the test was unable to be completed.

Figure 32: Clinic Base Station Unable to Complete Test Screen

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17. Next – 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.

18. From the Test Selection screen, the Clinic Base Station will indicate a green checkmark that the test has completed.
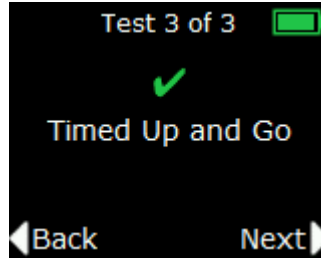
Figure 33: Clinic Base Station Test Complete Screen - TUG

19. Repeat Steps 6 through 18 for all tests in the Clinic Base Station Test Plan.

8.6.6. Performing a Level Walking Test with the Clinic Base Station

The Clinic Base Station System allows you to perform an "on-demand" data collection from a patient's CTE Implant or CanarE device while that patient performs a Level Walking test for the time selected in the Test Plan.

TIP: Verify the time entered in the patient's Test Plan for Level Walking is adequate for the patient to complete the test. Twenty (20) seconds of steady state walking is recommended for this test in order to process multiple gait cycles from the patient's data.

To perform the Level Walking Test with the Clinic Base Station (Figure 35):

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.
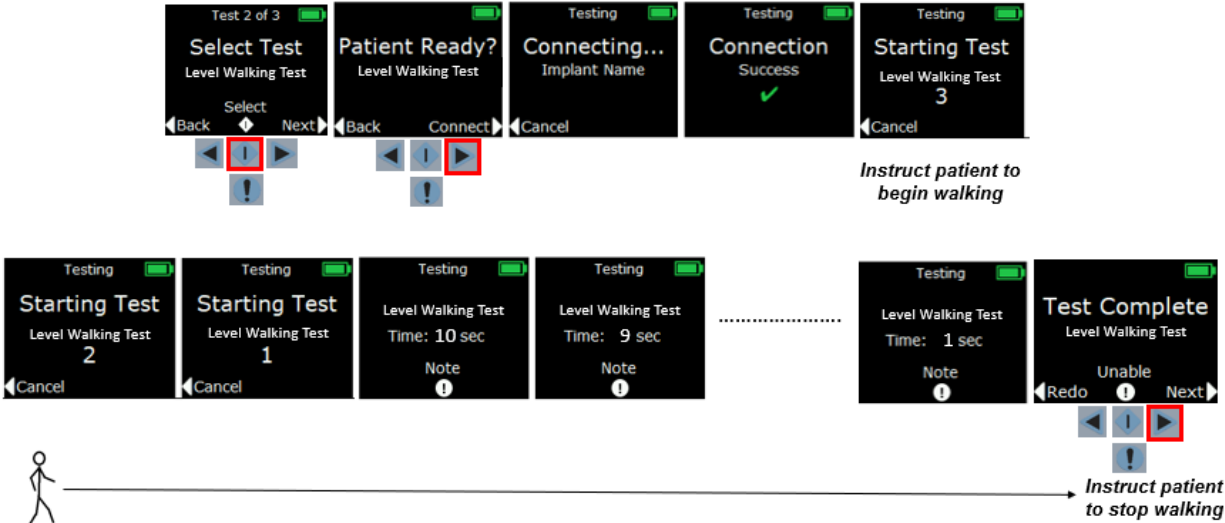

Figure 34: Test Complete Screen – Level Walking

Figure 35: Level Walking Test Overview

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8.6.7. Performing a Stair Climb Test with the Clinic Base Station

The Clinic Base Station System allows you to perform an "on-demand" data collection from a patient's CTE Implant or CanarE device while that patient performs a Stair Climb Test (SCT) for the period selected in the Test Plan.

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

TIP: Verify the time entered in the patient's Test Plan for a SCT is adequate for the patient to complete the test.

To perform the SCT with the Clinic Base Station (Figure 37):

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.

2. Select the SCT Ascend (Up) or SCT Descend (Down) 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.

Figure 36: Test Complete Screen for the SCT – Walking Up Stairs

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8. From the Test Selection screen, the Clinic Base Station will indicate a green check mark that the test has completed.
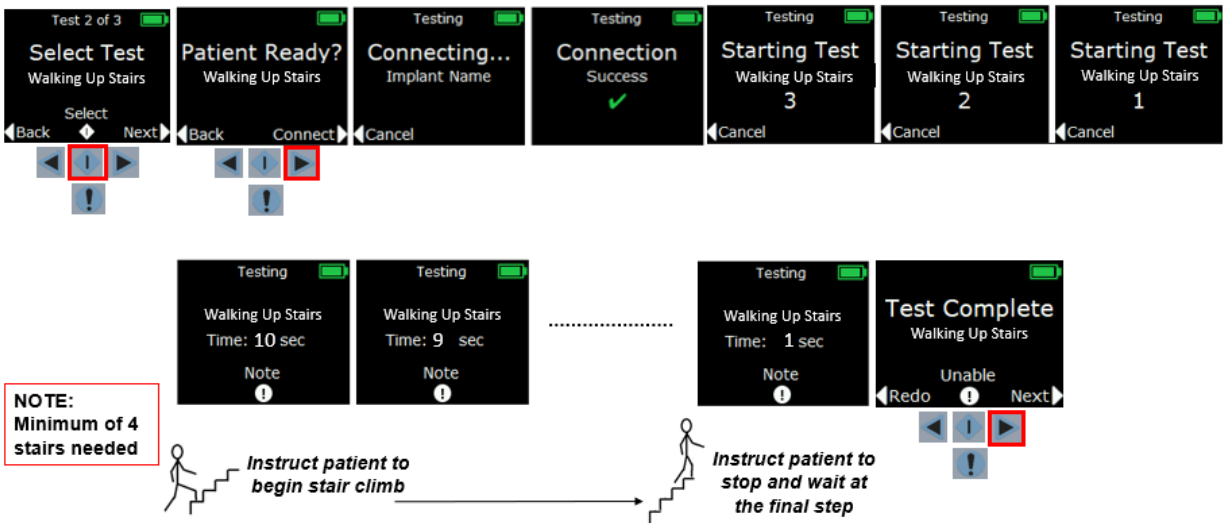
Figure 37: Stair Climb Test Overview (Ascending Stairs shown; instructions are identical for Descending Stairs, not shown)

8.6.8. Performing a Prone ROM Test with the Clinic Base Station

The Clinic Base Station System allows you to perform an "on-demand" data collection from a patient's CTE Implant or CanarE device while that patient performs a ROM test in the prone position for the period selected in the Test Plan.

- The Active ROM: the patient flexes and extends their knee without clinician assistance.
- The Passive ROM: the patient is relaxed while the clinician guides the flexion-extension movement of the patient's knee.

TIP: Verify that the time entered in the patient's Test Plan for the ROM Test is adequate for the patient to complete the test.

To perform the Prone ROM test (Active or Passive) with the Clinic Base Station:

1. Instruct the patient to lay in prone position on an exam table as shown in Figure 38. 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.

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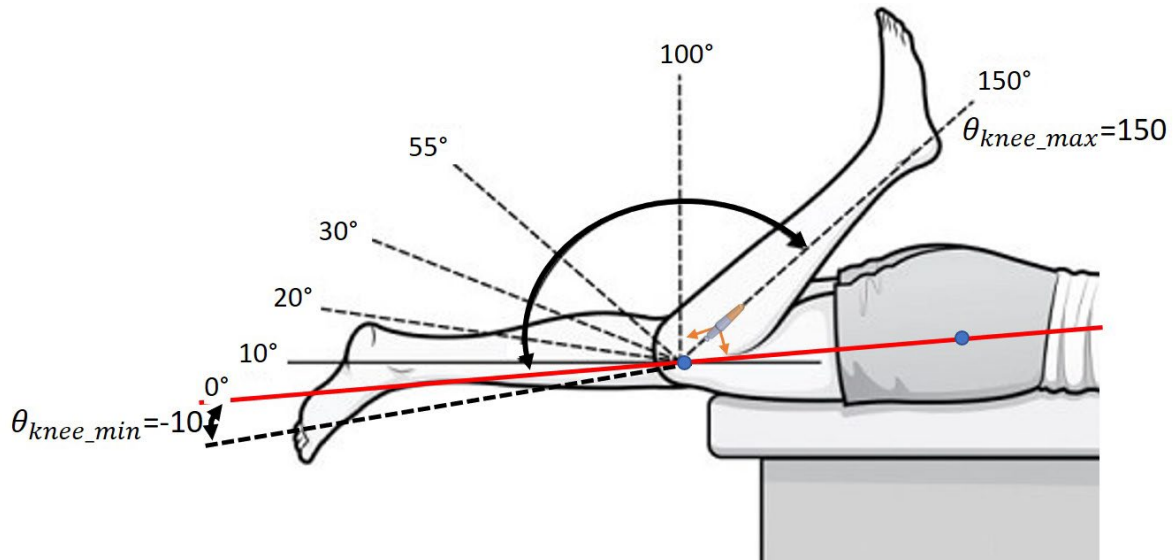
Figure 38: ROM Test Patient Positioning

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.

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8. The Clinic Base Station begins the countdown.

9. 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.

10. 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.

11. 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.

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

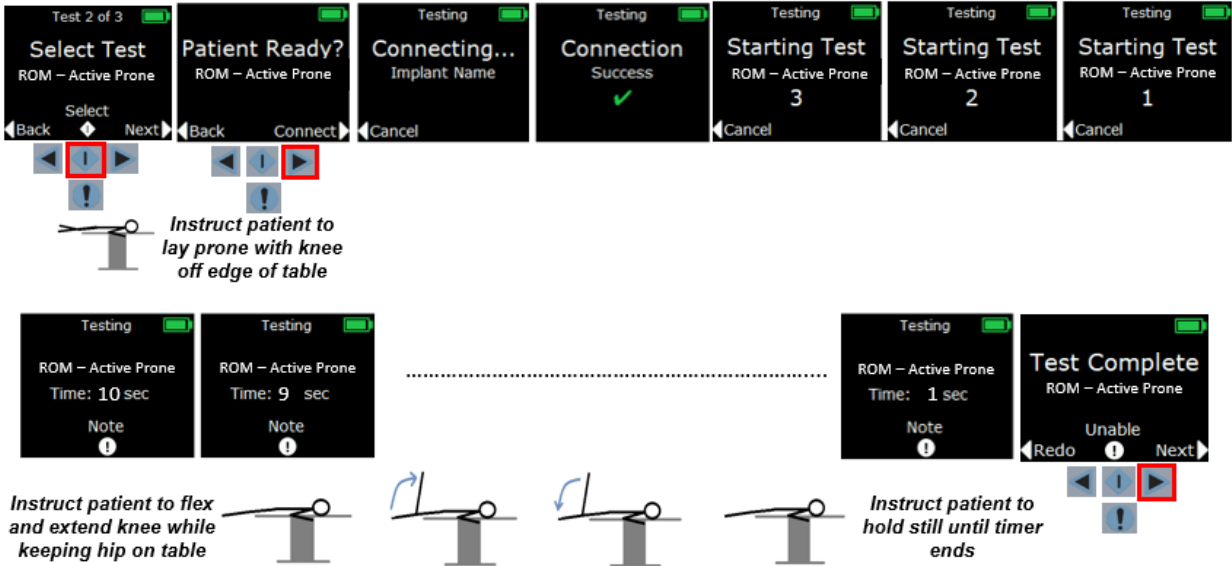
Figure 39: Test Complete Screen – ROM Active Prone

Figure 40: ROM Test Overview

8.6.9. Performing a Timed Up and Go Test with the Clinic Base Station

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The Clinic Base Station System allows you to perform an "on-demand" data collection from a patient's CTE Implant or CanarE device while that patient performs a Timed Up and Go test (TUG) for the period selected in the Test Plan.

TIP: Verify that the time entered in the patient's Test Plan for a TUG Test is adequate for the patient to complete the test.

To perform the TUG Test with the Clinic Base Station.

1. 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.

2. Select the TUG Test on the Clinic Base Station.

3. Verify the patient is ready.

4. Press the right Toggle Button on the Clinic Base Station to connect to the patient's CTE Implant or CanarE device.

5. The Clinic Base Station begins the countdown.

6. Wait for the data collection to begin before starting the TUG Test.

    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 as shown in Figure 41 if the Event Mark button was pressed. This saves the test start time in the data.
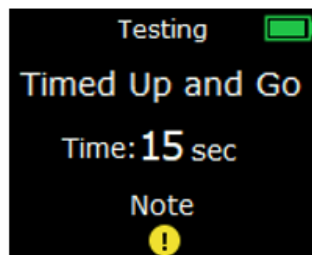
Figure 41: Clinic Base Station Timed Up and Go Event Marker Button Pressed at the Start Screen

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 yellow as shown in Figure 42 if the Event Mark button was pressed. 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.

    NOTE: If the Event Mark button presses do not align with the patient starting and stopping the test, test result data may be affected.
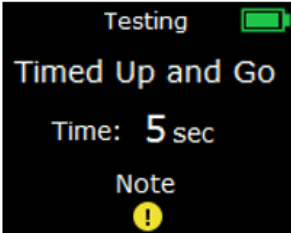
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Figure 42: Clinic Base Station Timed Up and Go Event Marker Button Pressed at the Stop Screen

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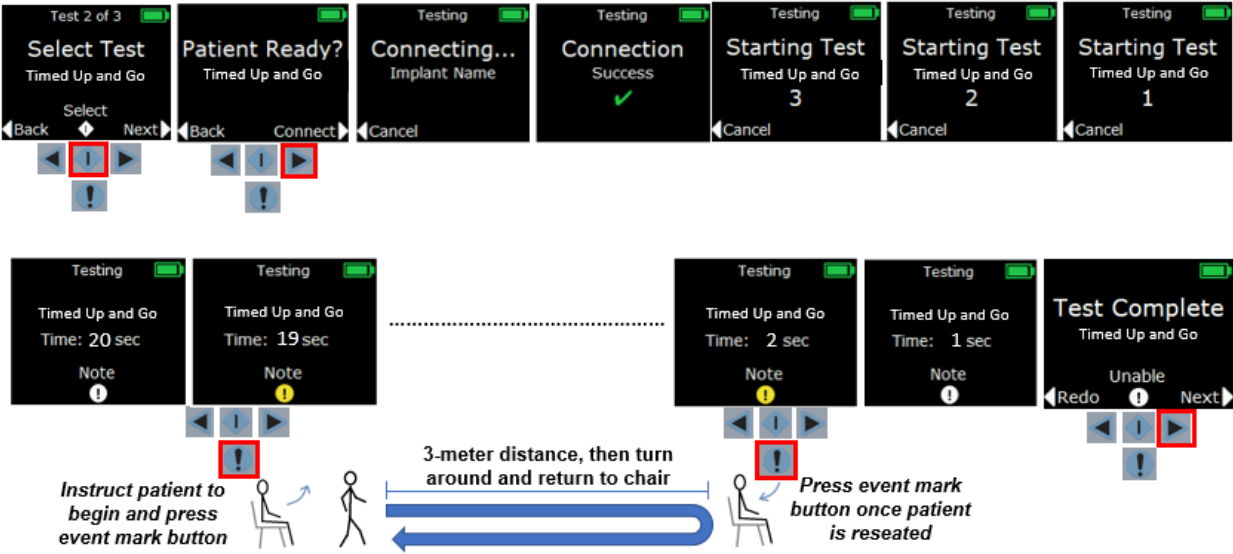

Figure 43: Test Complete Screen - TUG

Figure 44: TUG Test Overview

8.6.10. Performing a 360 Degree Turn Test with the Clinic Base Station

The Clinic Base Station System allows you to perform an "on-demand" data collection from a patient's CTE Implant or CanarE device while that patient performs a 360 Degree Turn test for the period selected in the Test Plan.

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TIP: Verify that the time entered in the patient's Test Plan for a 360 Degree Turn Test is adequate for the patient to complete the test.

To perform the 360 Degree Turn Test with the Clinic Base Station, instruct the patient on the test method to use.

>   **NOTE:** To perform a 360 Degree Turn Test, a patient turns in a complete circle (360 degrees) while the time to complete is recorded.

1. Select the 360 Degree Turn Test on the Clinic Base Station.

2. Verify that the patient is ready.

3. Press the right Toggle Button on the Clinic Base Station to connect to the patient's CTE Implant or CanarE device.

4. The Clinic Base Station begins the countdown.

5. Wait for the data collection to begin before starting the 360 Degree Turn 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 as shown in Figure 45 if it has been pressed. This saves the start time of the test.
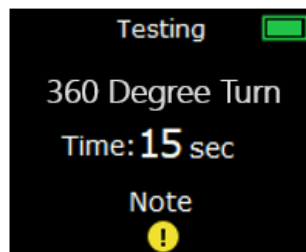
Figure 45: Clinic Base 360 Degree Turn Event Marker Button Pressed at the Start Screen

7. 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 as shown in Figure 46 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.
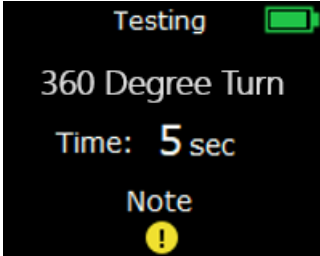
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Figure 46: Clinic Base Station 360 Degree Turn Event Marker Button Pressed at the Stop Screen
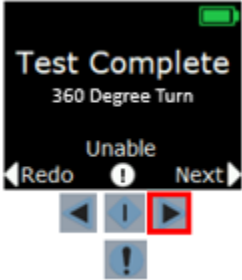
8. Select **Next** on the **Test Complete** screen.

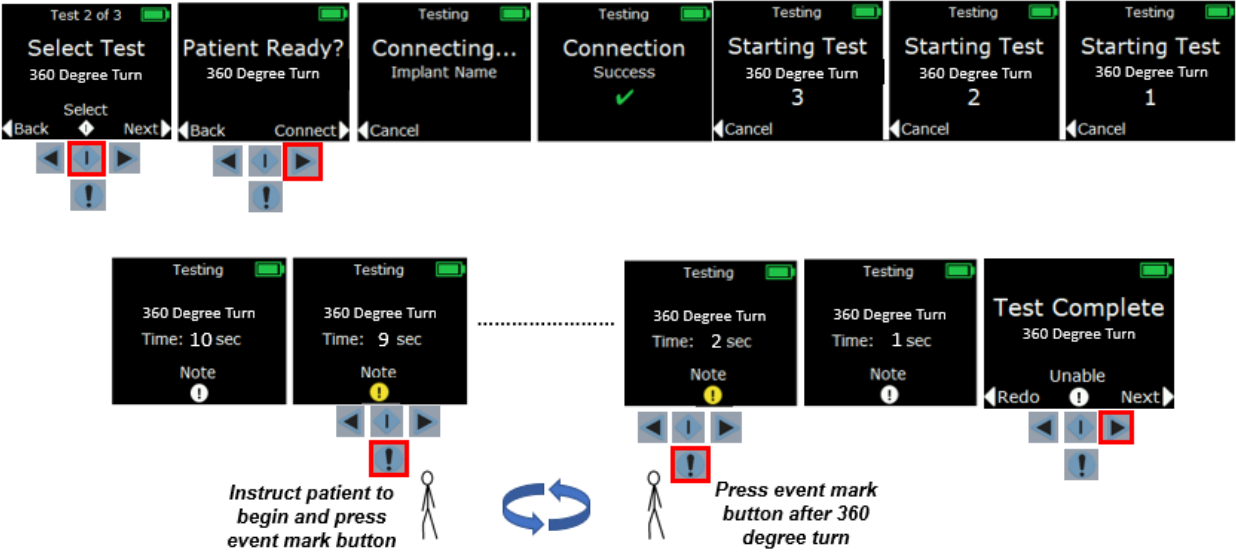*Figure 47: Test Complete Screen – 360 Degree Turn Test*

Figure 48: 360 Degree Turn Test Overview

8.6.11. Finishing the Test Plan and Uploading Patient Kinematic Data with the Clinic Base Station

1. When you have finished testing, use the right Toggle Button on the Clinic Base Station to scroll to the **Finish Testing** screen as shown in Figure 49.

   NOTE: You may finish testing without completing all tests in the predetermined Test Plan.

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Figure 49: Clinic Base Station Finish Testing Screen. All tests complete (left); tests remaining (right).

2. Push the **Select** button to finish testing.

3. The Clinic Base Station will confirm if you would like to collect the testing data from the patient's CTE or CanarE device.

4. Verify that the Clinic Base Station is within six (6) feet of the patient's device and press the right Toggle Button to collect the patient's device data.

Figure 50: Clinic Base Station Collect Data Screen

NOTE: After test data has been collected, it will need to be transferred to the Clinic App. You cannot go back and perform additional testing; it is not permitted at this point. Additional testing would require you to create a new Test Plan in the Clinic App, the patient going through the entire testing process using the Clinic Base Station again, and a test data transfer to the Clinic App.

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 as shown in Figure 51.

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Figure 51: Clinic Base Station Connecting to Implant, Collecting, and Saving Data Screens

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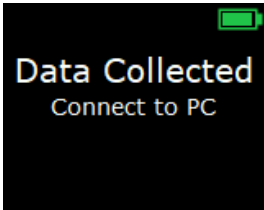

Figure 52: Clinic Base Station Data Collected Screen

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 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.
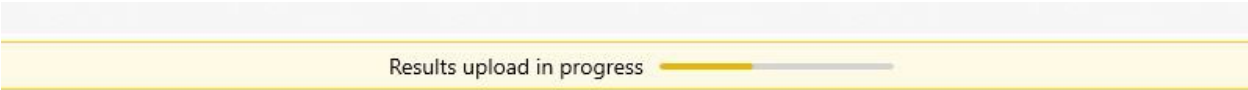

Figure 53: Clinic App Data Upload in Progress Screen

Figure 54: Clinic App Data Upload Complete Screen

8.7. Reviewing Patient Test Results

The CMCEP is processed in the Canary Cloud after receiving a patient's CTE and/or CanarE device data from the Clinic Base Station. Test results can be reviewed in the Clinic App. The subsequent sections describe the CMCEP outputs for each test.

NOTE: An internet connection is required for processing and viewing a patient's test data.

1. Login to the Clinic App to search and select the desired patient.

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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.

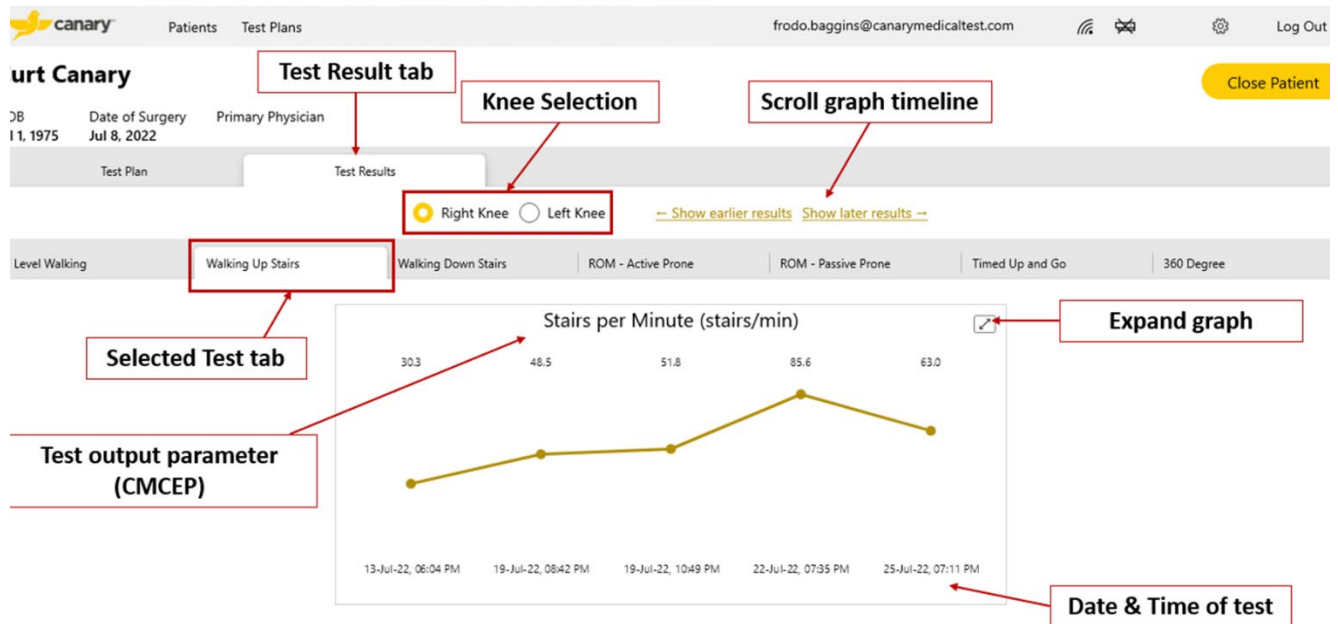Figure 55 illustrates the selected patient's right knee, Walking Up Stairs test results.

Figure 55: Clinic App Test Results Screen

8.7.1. Example of a Level Walking Test Report in the Clinic App

After the raw kinematic data has been uploaded from the CTE Implant or CanarE device to the Canary Cloud, the data is processed and the following CMCEP is reported:

Table 7: Level Walking Test CMCEP

Parameter	Description	Units
Walking Speed	Mean sagittal plane distance walked per unit of time. Derived from acceleration sensor data.	Meters per second (m/s)
Cadence	Mean steps per minute. Derived from two consecutive peak angular velocities.	Steps per minute (steps/min)
Stride Length	Mean anterior distance traveled over one gait cycle.	Meters (m)
Knee ROM	Mean sagittal plane functional knee joint range of motion when walking. Difference between maximum and minimum knee joint flexion.	Degrees (°)
Tibia ROM	Mean sagittal plane range of motion of the tibia with respect to the floor. Difference between the minimum and maximum tibia to floor angle.	Degrees (°)

The range of motion measurements are schematically illustrated in Figure 56 for a right leg motion through one gait cycle, where the angle α is the angle calculated based on a combination of tabular hip and femur reference data and the Tibia ROM data.
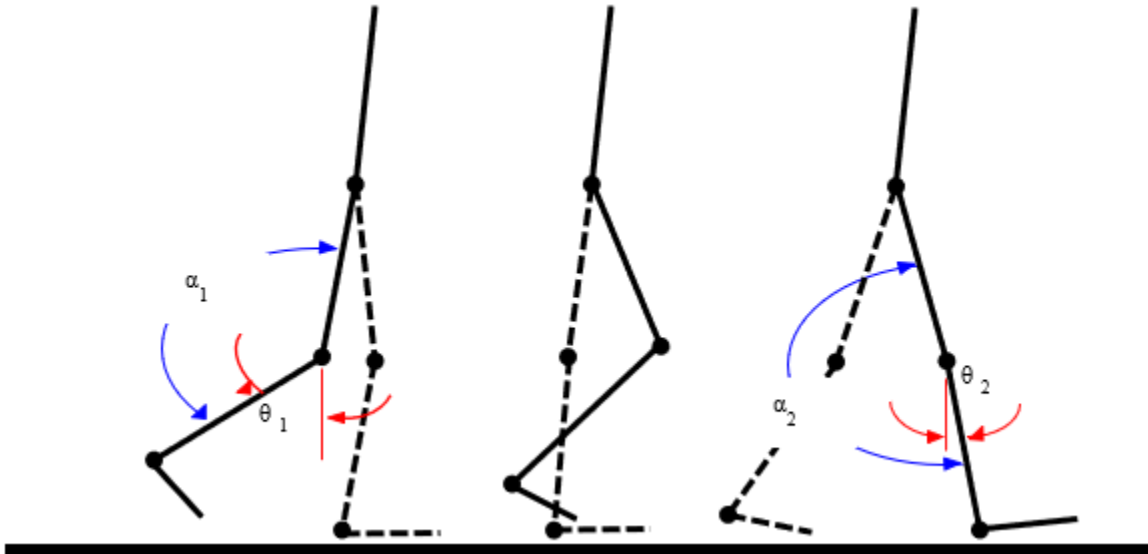
Figure 56: Schematic of Right Leg Motion. Tibia ROM = θ1 + θ2 and Knee ROM = α2 – α1

8.7.2. Stair Climb Test Report in the Clinic App

After the raw kinematic data has been uploaded from the device to the Canary Cloud, the data is processed and the following CMCEP is reported:

Table 8: Stair Climb Test CMCEP

Parameter	Description	Units
Stairs per minute	Mean stairs per minute when ascending or descending stairs	Stairs per min

8.7.3. Prone ROM (Active or Passive) Test Report in the Clinic App

After the raw kinematic data has been uploaded from the device to the Canary Cloud, the data is processed and the following CMCEP is reported:

Table 9: Prone ROM CMCEP

Parameter	Description	Units
Active prone knee ROM	Knee ROM (full extension to maximum flexion) under unassisted volitional movement in the sagittal plane	Degrees
Passive prone knee ROM	Knee ROM (full extension to maximum flexion) with the HCP assisting the movement in the sagittal plane	Degrees

The Prone ROM measurement is schematically illustrated in Figure 57 for a right-leg motion. The Prone ROM measurement will account for hyperextension.

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$$Knee\ ROM = \theta_{knee\_max} - \theta_{knee\_min} = 150 - (-10) = 160 \text{ deg}$$
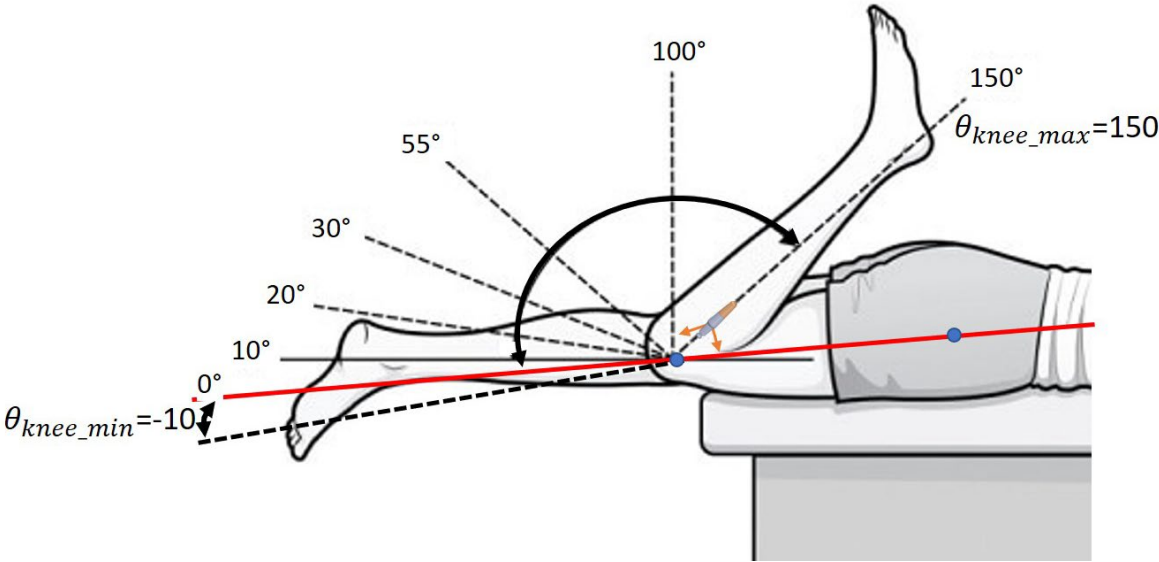

Figure 57: ROM Test Patient Positioning

8.7.4. Timed Up and Go Test Report in the Clinic App

After the raw kinematic data has been uploaded from the device to the Canary Cloud, the data is processed and the following CMCEP is reported:

Table 10: Timed Up and Go CMCEP

Parameter	Description	Units
TUG time	Total time to complete the Timed Up and Go test	seconds

8.7.5. 360 Degree Turn Test Report in the Clinic App

After the raw kinematic data has been uploaded from the device to the Canary Cloud, the data is processed, and the following CMCEP is reported:

Table 11: 360 Degree Turn CMCEP

Parameter	Description	Units
360 degree turn time	Total time to complete the 360 degree turn in place	seconds

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9. Data Security and Patient Privacy

All communication between the CTE Implant or CanarE devices and the Clinic Base Station employs a unique communication protocol where each device has a unique radio ID assigned to it in manufacturing. Clinic Base Stations can communicate with only one CTE or CanarE at a time using this radio ID.

NOTE: A patient could potentially have two CTE Implants (one in each knee) **however, only one implant will operate with** one Clinic Base Station at a time in that scenario.

The communication between the Clinic Base Station and the device(s) is encrypted with a unique encryption key assigned to it in manufacturing. In addition, communication integrity as well as data integrity checks are applied to the data received at both ends.

The Canary Medical Cloud Platform is designed for assuring that Private Health Information is protected. When the Clinic App is set up, a secure connection is established between the Clinic App and the Canary Cloud and is in effect for all communication thereafter. The communication and data are checked for integrity by the Cloud application before it is processed to output to the CMCEP.

Patients must consent to the CTE Implant or CanarE data collection, storage, analysis, and sharing their device and basic personal and health data with HCP(s) they designate to provide their healthcare. As such, data will be identifiable to their healthcare providers and authorized administrators (as necessary) of the Canary Medical Clinic Base Station System. The patient will have the right to be forgotten and will have the ability to turn off the device data collection after a minimum required time for data generation. If the patient does not wish to consent, they can receive other options from their healthcare provider.

Each HCP is assigned a unique username and will be prompted to enter a password at the login for logging into their account each time thereafter and for accessing the Clinic App.

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10. Component Maintenance

10.1. Updating the Clinic Base Station

This section describes how to apply system updates to the Clinic Base Station.

1. Launch and log into the Clinic App as described in Section 8.1.

   NOTE: An internet connection is required to download Clinic Base Station updates.

2. Connect the Clinic Base Station to the Laptop and power it on as described in Section 8.2.

3. If an update is available, select to update the Clinic Base Station displayed in the Clinic App notification. The Clinic App will automatically download the update to the Clinic Base Station.

   NOTE: Do not disconnect the Clinic Base Station while the update is downloading.

   NOTE: The Clinic App will not allow you to download test plans to a Clinic Base Station that requires an update.

10.2. Updating the Clinic App

This section describes how to update the Clinic App.

1. Launch and log into the Clinic App as described in Section 8.1.

   NOTE: An internet connection is required to download Clinic App updates.

2. Typically, the Clinic App will automatically update. If it displays a notification for an update, select the option to update the Clinic App. It will automatically download the update.

   NOTE: Do not close the Clinic App while the update is downloading.

   NOTE: If an update to the Clinic App is required, use of the Clinic App will be restricted until the update has completed.

10.3. Clinic Base Station Cleaning

Maintain the Clinic Base Station(s) and accessories by keeping them clean, dry, and free of surrounding clutter.

The Clinic Base Station and Clinic Laptop may be cleaned and disinfected using CaviWipes® as necessary following the steps below. CaviWipes® is an intermediate level disinfectant (10^{-3} SAL) and is effective for cleaning and disinfecting the OR Base Station, Bar Code Scanner and laptop.

1. Wipe device with a CaviWipes to remove soil.

2. Using a fresh wipe, wipe down to ensure the CaviWipes solution is in contact with seams, creases, crevices, and mated surfaces.

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3. Allow to remain visibly wet for 2 minutes, per CaviWipes manufacturer recommendation.

4. Allow to air dry at ambient temperature.

The following solutions have been tested for safe cleaning of the Clinic Base Station. Wipe the Clinic Base Station after each use with a soft cloth dampened with one of these solutions:

1. 1:10 Bleach Solution

2. 1:10 Mild Detergent Solution

3. Ammonia Solution (RTU)

4. 70% Isopropyl Alcohol

5. 0.5% Hydrogen Peroxide

6. Phenolic germicidal detergent solution (RTU)

7. Iodophor germicidal detergent solution (RTU)

WARNING: Do not immerse the Clinic Base Station or accessories in water or cleaning agents as this could cause electrocution.

NOTE: The Clinic Base Station and accessories are resilient to dust, lint, and light (including sunlight). However, lint or dust may get into the USB port or the port may become degraded and interfere with power to or communicate with the Clinic Base Station or accessories. Do not attempt to clean or repair the USB ports. Instead, contact Canary Medical for a replacement.

11. Disposal

Contact your local authorities to determine the proper disposal method of Clinic Base Station Units and accessories as electronics waste or return them to Canary Medical.

12. Troubleshooting

12.1. Servicing

If a Clinic Base Station or accessory is not working properly or even changes in performance, see the instructions in the next section for troubleshooting and potential solutions to a problem. If the issue cannot be fixed, please call Canary Medical for instructions on how to further troubleshoot or return the unit for replacement.

12.2. Clinic App Troubleshooting

The following list of steps will generally solve issues encountered in the Clinic App:

1. Verify the username and password login credentials when entered.

2. Verify that an internet connection has been established.

3. Verify that the Clinic App does not have an outstanding update. If it does, follow the directions in Section 10.2 to update it.

4. Verify that all required fields have been entered on the screen.

    a. Creating a new patient – all fields must be entered to save the new patient to your account.

    b. Sending a test plan to the Clinic Base Station – verify:

        i. The correct patient was selected.

        ii. The CTE or CanarE device was selected.

            • CTE – verify that the left or right knee was selected (if applicable).

            • CanarE – select the left or right knee as well as the desired device to be used.

        iii. The Clinic Base Station is connected to the Laptop and powered on.

        iv. A test plan was selected. If a custom plan was selected or modified, the test plan must be saved before sending it to the Clinic Base Station.

5. Log out and log back in.

6. Restart the Laptop.

7. If the problem persists, contact Canary Support.

## 12.3. Clinic Base Station and CTE or CanarE Connection Troubleshooting

It is possible that certain wireless Wi-Fi routers, Wi-Fi- boosters, and Bluetooth devices (such as mobile phones, wireless audio devices, or computers) may interfere with the Clinic Base Station wireless communications. If you experience delays in Clinic Base Station communications,

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move either the Clinic Base Station or the other wireless device(s) away from each other or turn the conflicting device(s) off.

## 12.4. Clinic Base Station Troubleshooting

1. If the Clinic Base Station screen displays the **Self-Test Failed** message shown in Figure 58, press the right Toggle Button to reset the Clinic Base Station. If the problem persists, contact Canary Support.

   NOTE: A reset can also be performed by connecting and then disconnecting the Clinic Base Station from the Laptop. Wait 10 seconds before reconnecting them.
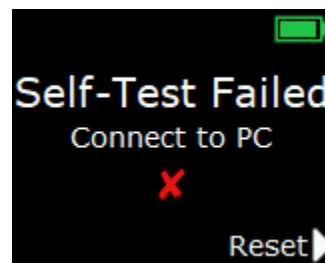
Figure 58: Clinic Base Station Self-Test Failed

2. If the Clinic Base Station is turned on without a test plan downloaded and is disconnected from the Laptop or power, the screen will display **No Plan Loaded** as shown in Figure 59. Reconnect the Clinic Base Station to the Laptop and download a test plan for the patient.
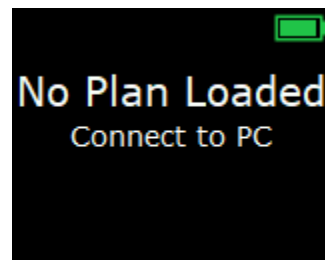
*Figure 59: Clinic Base Station No Plan Loaded*

3. If the Clinic Base Station is turned on with a test plan loaded but the date and/or time has not been set, the screen will display **Plan Loaded** as shown in Figure 60. Connect the Clinic Base Station to the Laptop and re-send the test plan.
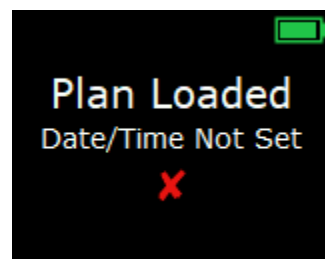
Figure 60: Clinic Base Station Date/Time Not Set

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4. If the Clinic Base Station displays **CanarE Needs Update**:

    1) If using a CanarE, see Section 10.1 of the CanarE System Instructions for Use (K03-CNE-300005) for updating the CanarE firmware, or

    2) If using a CTE, please contact Canary Medical's customer service for support.
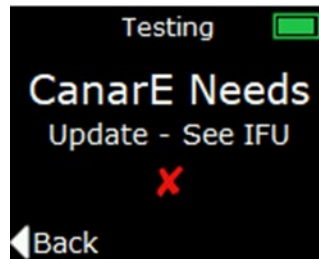
Figure 61: Clinic Base Station CanarE/CTE Update

13. Component Specifications

Table 12: Clinic Base Station System Specifications

Clinic Base Station Unit	Specification
Weight	< 1 lb
Dimensions	206.6 x 70.0 x 15.0 mm
Power Source	External Supply: 100-240V 50- 60 Hz Class II Base Station: internally battery-powered
Mode of Operation	**Operational Modes:** • Power on (w/ self-test) • Normal operation • Fault (self-test failure) **Mode of Operation (Non-continuous):** The HCP uses the Clinic Base Station System before, during, and after on demand clinic data collection. It is used to create patients and test plans and initiate on demand data collection, as well as to review data. The Clinic Base Station System consists of a Clinic Base Station, and a dedicated Clinic Laptop loaded with the Clinic App.
Recommended Operating Conditions	**Temperature:** 15°C to 25°C **Relative Humidity**: 10% to 90% (non-condensing) **Atmospheric Pressure**: 70 kPa – 106 kPa
Storage Conditions	**Temperature:** 15°C to 25°C **Relative Humidity**: 10% to 90% (non-condensing)
Transport Conditions (Packaging Tested to ISTA 3A Standard)	**Temperature:** -18°C to 60°C **Relative Humidity**: 10% to 90% (non-condensing) **Atmospheric Pressure**: 50 kPa to 106 kPa
Protection from Ingress of Liquids and Particles	Per IEC-60529, Clinic Base Station rated as IP22.
Audible Output Levels	None. (Not applicable.)
Clinic Laptop	**Specification**
Manufacturer	Dell
Operating System	Windows 10
Power Source	Laptop Power Supply: 100-240V 50-60 Hz Class I

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14. Electrical Safety and Standard

14.1. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter is intended for use in the electromagnetic environment specified in Table 13. The customer or the transmitter user should verify that it is used in such an environment.

It is possible that certain wireless Wi-Fi routers, Wi-Fi boosters, and Bluetooth devices (such as mobile phones, wireless audio devices, or computers) may interfere with the Base Station wireless communications. If you experience delays in Base Station communications, try moving either the Base Station or other wireless device(s) away from each other.

14.2. Electromagnetic Immunity Specifications

Table 13. Electromagnetic Immunity Specifications

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts [a) l) o)]	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges [a) b) j) o)] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges [a) b) j) k) o)] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V [m)] 0,15 MHz – 80 MHz 6 V [m)] in ISM bands between 0,15 MHz and 80 MHz [n)] 80 % AM at 1 kHz [e)]	3 V [m)] 0,15 MHz – 80 MHz 6 V [m)] in ISM and amateur radio bands between 0,15 MHz and 80 MHz [n)] 80 % AM at 1 kHz [e)]
Voltage dips [f) p) r)]	IEC 61000-4-11	0 % U_T; 0,5 cycle [g)] At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)] 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles [h)] Single phase: at 0°	
Voltage interruptions [f) i) o) r)]	IEC 61000-4-11	0 % U_T; 250/300 cycle [h)]	

a) This test applies only to output lines intended to connect directly to outdoor cables.

b) SIP/SOPS where the maximum cable length is less than 3m (10 feet) in length are excluded.

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c) Testing may be performed at other modulation frequencies identified by the Risk Management Process.

d) Calibration for current injection clamps shall be performed in a 150.

e) Connectors shall be tested per section 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in *Figure 7: Clinic Base Station Battery Charge Status Screens* of the general standard, applied in a bent or straight position.

f) Capacitive coupling shall be used.

g) If the frequency stepping skips over an industrial, scientific and medical (ISM) or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

h) r.m.s., before modulation is applied.

i) The ISM bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

14.3. **Electromagnetic Emissions**

The CTE and CanarE devices are intended for use in the electromagnetic environment specified in Table 14. Verify that the transmitter is used in such an environment.

Table 14. Electromagnetic Emission

Phenomenon	Professional Healthcare Facility Environment [a]	Home Healthcare Environment
Conducted and radiated RF Emissions	CISPR 11	CISPR 11 [c), d)]
Harmonic distortion	See IEC 61000-3-2 [b]	See IEC 61000-3-2
Voltage fluctuations and flicker	See IEC 61000-3-3 [b]	See IEC 61000-3-3

a) This test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEMS used there will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.

b) ME EQUIPMENT and ME SYSTEMS intended for use in aircraft shall meet the RF EMISSIONS requirements of ISO 7137. The conducted RF EMISSIONS test is applicable only to ME EQUIPMENT and ME SYSTEMS that are intended to be connected to aircraft power. ISO 7137 is identical to RTCA DO-160C:1989 and

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EUROCAE ED- 14C:1989. The latest editions are RTCA DO-160G:2010 and EUROCAE ED-14G:2011. Therefore, use of Section 21 (and category M) of a more recent edition, e.g., [39] or [40], should be considered.

c) Standards applicable to other modes or EM ENVIRONMENTS of transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25 and ISO 7637-2.

14.4. FCC Disclosure

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service.

Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

For additional FCC compliance information, please visit https://canarymedical.com/compliance-fcc.

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15. Warranty

Canary Medical (or such other legal entity as may be referred to as manufacturer on the labeling of this device, hereinafter "Canary Medical") warrants the Canary Clinic Base Station (hereinafter "Product") to the original purchaser of the Product against defects in material and workmanship for a period of one (1) year from the date the Product is purchased. During the warranty period, Canary Medical will replace or repair, at its discretion, any defective Product, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a Product is replaced, the warranty period will not be extended past its original expiration date. This warranty is valid only if the Product is used in accordance and for the purposes set forth in the manufacturer's instructions.

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16. Patents and Trademarks
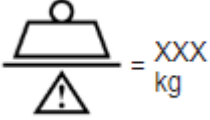
All trademarks are the exclusive property of Canary Medical and its Subsidiaries with the exception of CaviWipes® which is the property of its respective owner.

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17. Symbols Glossary

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
	Canary Medical Logo		
	The name of the device's manufacturer	ISO 7000 —3082 Graphical symbols for use on equipment -- Registered symbols	Manufacturer
REF	The catalogue or order number assigned to the device by the manufacturer	ISO 7000 — 2493 Graphical symbols for use on equipment -- Registered symbols	Catalogue Number
SN	The unique serial number assigned to the device by the manufacturer	ISO 7000 — 2498 Graphical symbols for use on equipment -- Registered symbols	Serial Number
EDI	Computer-to-computer exchange of business documents in standardized formats		Electronic Data Interchange
	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 clause 5.4.3	Consult instructions for use or consult electronic instructions for use.
	Informs the user not to use the device after the date listed on the package The date is formatted YYYY-MM-DD according to ISO 8601	ISO 7000-2607 Graphical symbols for use on equipment -- Registered symbols	Use by date
		ISO 14708-1, clause 9.7 and 11.5 Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	
		ISO 8601-1 A2.1 Date and time — Representations for information interchange — Part 1: Basic rules	
	Date the device was manufactured	ISO 14708-1, clause 9.6 and 11.6 Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	Date of Manufacture.
	Directs the user to read the instructions for use	ISO 7010-M002 Graphical symbols -- Safety colors and	Refer to instruction manual/booklet

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
		safety signs -- Registered safety signs	
		IEC 60601-1 7.2.3 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	
Rx ONLY	For prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.	
	Instructs the transporter of the device package to keep the device package dry	ISO 7000-0626 Graphical symbols for use on equipment -- Registered symbols	Keep dry.
		ISO 15223-1 clause 5.3.4 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	
	Instructs the transporter of the device package to protect the device package from sunlight	ISO 7000-0624 Graphical symbols for use on equipment -- Registered symbols	Keep away from sunlight
		ISO 15223-1 clause 5.3.2 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	
	Transport and storage temperature limits See Table 12 for additional information.	ISO 15223-1 clause 5.3.5-6 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Temperature limit
	Transport and storage humidity limit ISO 7000-2620 See Table 12 for additional information	ISO 15223-1 clause 5.3.8 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Humidity limitation
	Directs the user not to use the device if the package has been opened or damaged	ISO 15223-1 clause 5.2.8 ISO 11607-1 clause 10	Do not use if package is damaged
	Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions	ISO 15223-1 clause 5.4.4	Caution

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Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
	Identifies electrical equipment designed for indoor use	IEC 60417 — 5957 Graphical symbols for use on equipment	For indoor use only
	Equipment mass including safe working load XXX indicates specified weight (used in accordance with IEC 60601-1, clause 7.2.21		
	Non-ionizing radiation includes RF ISO 7000-5140	IEC 60601-1-2:2007, clause 5.1.1	Non-ionizing electromagnetic radiation
	Direct current	ISO 7000-5031 Graphical symbols for use on equipment -- Registered symbols	Equipment is suitable for direct current only
IP22	Protected from touch by fingers and objects greater than 12 millimeters, and Protected from water spray less than 15 degrees from vertical.	IEC 60601-1, (IEC 60529) clause 6.3; Table D.3	Degree of protection
(01)00860003118313 (21)123456	Data Matrix Barcode intended provide single, globally harmonized positive identification of medical devices through distribution and use, requiring the label of devices to bear a globally unique device identifier (to be conveyed by using Automatic Identification and Data Capture	21 CFR 830	Unique Device Identification
+H124435570002141B *+$123456A20B_*			Health Industry Bar Code (HIBC)

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