

Persona IQ[®]

THE SMART KNEE[™]

**CANARY canturio[™] Tibial Extension
with CHIRP[™] System**

Patient Manual



Read this manual carefully. If you have additional questions after reading this manual, contact your doctor.

How to Contact Canary Medical

Customer Assistance Phone: 1-833-692-2627

E-mail: support@canarymedical.com

Internet: www.canarymedical.com

Mail: Canary Medical USA LLC

2710 Loker Ave. West, Suite 350

Carlsbad, CA 92010

Your Knee Implant Information*

Type	Zimmer Biomet Persona [®] The Personalized Knee [®] and CANARY canturio [™] Tibial Extension with CHIRP [®] System
Model Number	
Serial Number	
Implant Date	

Your Canary Medical Patient Registration Information

Website	
Username	
Password	

**Your health care provider can provide this information.*

Table of Contents

GLOSSARY	4
INTRODUCTION	6
SETTING UP YOUR PATIENT ACCOUNT	14
SETTING UP YOUR CHIRP HOME BASE STATION	23
YOUR PATIENT DASHBOARD	34
MAINTAINING YOUR CTE WITH CHIRP SYSTEM	38
TROUBLESHOOTING	42
FREQUENTLY ASKED QUESTIONS (FAQS)	43
SYMBOLS	46

Glossary

Cadence

The steps you take per minute, as measured by the CHIRP system.

Caregiver

An adult family member, friend, or personal assistant who can help you with your care and who you allow to have access to your personal and health information.

CHIRP®

This stands for Canary Health Implanted Reporting Processor. This is the software and electronics found within your CTE knee implant. The software and electronics collect information on your activity level and quality of movement after you receive your new knee.

CTE

Canturio™ Tibial Extension. The CTE is a part of the knee implant that will help to stabilize your new knee. It also contains software and electronics that will collect information about your activity level and how well you walk immediately after surgery and over a long period of time.

Distance

This is how far you have walked in miles on a given day as measured by the CHIRP system.

EHR

Electronic Health Record. This is the medical information stored electronically by your doctor's office and in your Patient Account. You have the right to access this information.

Gait

Refers to the manner or way in which a person walks.

Home Base Station

The unit placed in your home which collects activity information from your CTE knee implant and sends it to a website, where you and your doctor view it.

Patient Dashboard

Your page where you log in on the Canary Medical website to view information collected by the CTE and CHIRP system. Please note that the data collected each day will not be available on the dashboard until the following day.

Prosthesis

Medical term for your knee implant.

Range of Motion

This is a measure of how much your knee can bend and straighten.

Step Count

The number of steps you take during the most active part of your day.

Stride

The amount of distance covered between the time when one foot hits the ground and then the same foot hits the ground again.

USB Cable

A cable shipped with your CHIRP Home Base Station that allows it to connect with your computer.

TKA

Total Knee Arthroplasty. Also called total knee replacement. This is the replacement of your natural knee joint with an implant (prosthesis).

Walking Speed

This is a measure of how far you walk over a period of time.

Introduction

With the help of your doctor, you have decided to have a procedure called a total knee arthroplasty (TKA). TKA is also called total knee replacement. The TKA procedure replaces diseased or damaged parts of your natural knee joint with an implant (prosthesis) device.

The implant you will receive is a Persona[®] The Personalized Knee[®] with a CANARY canturio[®] Tibial Extension (CTE).

The CTE is a part of the knee implant that will help to stabilize your new knee. It also contains software and electronics that will collect information about your activity level and how well you walk immediately after surgery and over a long period of time.

The software and electronics are part of a technology package called the Canary Health Implanted Reporting Processor (CHIRP[®]). CHIRP allows information about how you are walking to be collected from your CTE implant. The data are processed and transmitted to a secure website where both you and your doctor will be able to view information about your activity level on your respective Dashboards. This helps your doctor to monitor your activity level between office visits during your post-TKA surgical care.

There are several steps in the process of receiving your knee implant and using your CHIRP System. They are generally outlined below:

1. Meet with your doctor and decide to go forward with TKA surgery, including the CTE implant.
2. Use the Quick Start Guide your doctor's office gave you, and this manual, to create a patient account. You must create an account prior to surgery to receive the CTE Implant.
3. Receive a Home Base Station and connection accessories. Along with your knee implant, this equipment is part of the CHIRP System.
4. Set up your Home Base Station using the instructions in this manual and a Quick Start Guide provided with the Home Base Station.
5. Have your TKA surgery.
6. Return home from the hospital or rehabilitation center.
7. Confirm your Home Base Station is still working correctly by checking the

green light on the unit.

8. After you return home, the Home Base Station will automatically start collecting and sending information from your CTE implant to the secure Canary Medical website.
9. View your activity on your Patient Dashboard, located on the Canary Medical website. You can start viewing data on the third day after your procedure.
10. Follow up with your doctor as directed.

The Quick Start Guide and this manual show you how to create your patient account and set up your Home Base Station so your CTE implant can start to collect information on day two after your surgery.

This manual also describes how to use the internet to view the data collected by your implant.

Finally, this manual answers other questions you may have about your knee implant with the CHIRP system.

Please read this information carefully. If you have additional questions about your knee replacement procedure, your knee implant with CTE, or the CHIRP system, please contact your doctor.

WARNING- The kinematic data from this device have not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision-making, and no data have been evaluated by FDA regarding clinical benefits.

Descriptive Information About Your Knee Implant with CANARY canturio[®] Tibial Extension with CHIRP[®] System

Intended Use / Indications for Use

Canturio™ Tibial Extension (CTE) with Canary Health implanted Reporting Process (CHIRP[®]) System is intended to provide objective kinematic data from the implanted medical device during a patient's total knee arthroplasty (TKA) post-surgical care.

The kinematic data are intended as an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery.

This device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension.

The objective kinematic data generated by the CTE with CHIRP System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit.

The CTE with CHIRP System is compatible with Zimmer Biomet Persona[®] The Personalized Knee[®] System.

Purpose of the Device

During your surgery, your surgeon will replace your natural knee joint with a knee implant (prosthesis). Your prosthesis will include a CTE with CHIRP, which does the following:

- Collects mobility data to help you and your doctor remotely monitor the following activity parameters:
 - Walking speed
 - Stride length
 - Candance
 - Step count
 - Distance walked
 - Tibia range of motion
 - Knee range of motion

- The added length that occurs with this device provides additional stabilization of the knee implant.

The software and electronics inside the CTE, along with the external Home Base Station unit, collects movement information from your implant. This information helps your doctor monitor your activity level after surgery and can support your doctor’s post-surgery recommendations concerning your rehabilitation. You can view your activity level that your doctor is monitoring by going on the Internet and viewing your Patient Dashboard. Your doctor views your data from the Physician Dashboard.

Your Knee Implant with CTE & CHIRP Components

The picture below portrays how the CTE connects to the Zimmer Biomet Persona® The Personalized Knee® tibial plate component.



The CTE outer surfaces are made with the following materials:

- Titanium alloy
- Natural PEEK (polyether ether ketone)
- Loctite M-31 CL Epoxy

Your CHIRP Home Base Station

To enable transmission of your CTE data to the Canary Medical Cloud for

analysis and display to you and your doctor, a Home Base Station, USB Data and Power Cable, and Wall Plug Adapter will be provided to you by your doctor. Instructions for setting up your Home Base Station are on the following pages.

The Home Base Station outer enclosure is made with the following materials:

- PC/ABS, Cycloy (polycarbonate/acrylonitrile-butadiene-styrene)
- Autotex Polyester

Contraindications

Who should not get the Canturio™ Tibial Extension?

You should not receive the CTE if you are undergoing cancer treatments at or in the proximity of the CTE using ionizing radiation. These treatments or procedures could damage the CTE.

The CTE Implant is longer than some other knee implants. Some patients can't get the CTE because they don't have enough space inside their bones for the implant to fit. The implant must fit properly to avoid bone damage. Your doctor will take measurements to ensure the CTE will work with your body.

Who should not get TKA surgery?

The following people should not get TKA surgery:

- People who have had a previous infection, either in the affected knee or in another part of the body, that could affect the new implant.
- People whose bone structure cannot support the new implant. This can be due to osteoporosis, bone loss, bones that are not fully formed, degeneration of the knee joint, etc.

The Zimmer Biomet Persona IQ® Smart Knee™ is not for use in patients who have:

- Previous history of infection in the affected joint and/or other local/ systemic infection that may affect the prosthetic joint
- Insufficient bone stock on femoral or tibial surfaces
- Skeletal immaturity
- Neuropathic arthropathy
- Osteoporosis or any loss of musculature or neuromuscular disease that compromises the affected limb
- A stable, painless arthrodesis in a satisfactory functional position
- Severe instability secondary to the absence of collateral ligament integrity

Patients who have rheumatoid arthritis (RA) accompanied by an ulcer of the skin or a history of recurrent breakdown of the skin should not get TKA because their risk of postoperative infection is greater. RA patients using steroids may also have increased risk of infection. Late infections in RA patients have been reported 24+ months postoperative.

Does knee implant surgery have risks?

All surgery has risks. Before your surgery, your doctor will explain the risks and benefits of your total knee replacement.

How can knee implant surgery help me?

Knee implant surgery may help you to move and walk better. After recovery, you may have less pain, since your damaged or injured knee joint will be replaced with a new implant.

What to expect after your TKA surgery with CANARY canturio® Tibial Extension

The CTE with CHIRP system will provide you and your doctor with information about your activity levels after your surgery. The activity level may help you and your doctor to know if your movement is what is anticipated by your doctor.

If you have questions about recovering after TKA surgery, such as how much pain to expect, how long it will take you to get better, and what medications you might need, talk to your doctor.

Will my implant have to be replaced?

Knee implants do eventually wear out for some patients, and there is always the possibility that your knee implant will have to be replaced. Talk to your doctor if you have questions or concerns about how long your implant should last.

Warning

WARNING - The kinematic data from this device has not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision-making, and no data have been evaluated by FDA regarding clinical benefits.

The CTE with CHIRP System is only compatible with the Zimmer Biomet Persona® The Personalized Knee® System.

Keep the USB cable out of reach of children because strangulation could result from baby or child entanglement in the charge cable.

Precautions

Use only the wall adapter and USB cable provided with the Base Station. Do not place your Home Base Station in direct sunlight.

Do not place your Home Base Station directly on or close to a heater which may cause electronics to overheat.

Cybersecurity

For additional data security, we recommend that you purchase and install software virus and malware protection software on your personal computer if it is not already installed and current.

Setting Up Your Patient Account

Canturio™ Tibial Extension (CTE) with CHIRP® System

Before you have your TKA surgery, follow the steps and screenshots below to set up your patient account.

After you complete your account setup, a Home Base Station and connection accessories will be provided to you. The Home Base Station will receive kinematic data from your CTE to send to your doctor to monitor your activity level post-surgery.

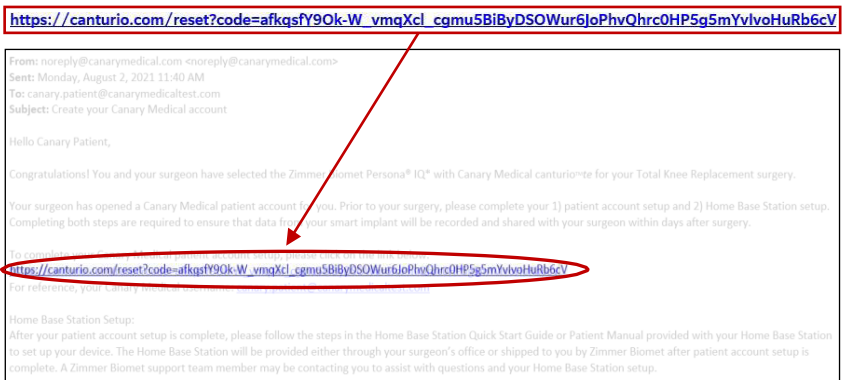
Zimmer Biomet mymobility® Users

If you already have an account in Zimmer Biomet's mymobility application, you do not have to create a Canary account (this process is automated for you). **Please skip the following section and proceed to the steps for "Setting Up Your CHIRP Home Base Station."**

You are not required to agree to the Terms and Conditions for receiving a CTE with CHIRP. Your doctor can provide you with a standard knee implant instead of the CTE with CHIRP System. You can also change your mind at any time before having your surgery.

If you do not have a Zimmer Biomet mymobility® account:

1. After leaving the doctor's office, check your email for a message containing instructions on how to set up your Canary patient account.
2. In the e-mail, click on the link, as circled in the screen shot example below.



https://canturio.com/reset?code=afkqsfY9Ok-W_vmqXcl_cgmu5BiByDSOWur6JoPhvQhrc0HP5g5mYvlvoHuRb6cV

From: noreply@canarymedical.com <noreply@canarymedical.com>
Sent: Monday, August 2, 2021 11:40 AM
To: canary.patient@canarymedicaltest.com
Subject: Create your Canary Medical account

Hello Canary Patient,

Congratulations! You and your surgeon have selected the Zimmer Biomet Persona® IQ* with Canary Medical canturio™ for your Total Knee Replacement surgery.

Your surgeon has opened a Canary Medical patient account for you. Prior to your surgery, please complete your 1) patient account setup and 2) Home Base Station setup. Completing both steps are required to ensure that data from your smart implant will be recorded and shared with your surgeon within days after surgery.

To complete your account setup, please click on the link below:

https://canturio.com/reset?code=afkqsfY9Ok-W_vmqXcl_cgmu5BiByDSOWur6JoPhvQhrc0HP5g5mYvlvoHuRb6cV

For reference, your Canary Medical account ID is: [XXXXXXXXXXXXXXXXXXXXXXXXXXXX](#)

Home Base Station Setup:
After your patient account setup is complete, please follow the steps in the Home Base Station Quick Start Guide or Patient Manual provided with your Home Base Station to set up your device. The Home Base Station will be provided either through your surgeon's office or shipped to you by Zimmer Biomet after patient account setup is complete. A Zimmer Biomet support team member may be contacting you to assist with questions and your Home Base Station setup.

3. Your username should already be filled in for you. If it is not, enter your email address. Your email address is your username.

Create a password. Your password must be a minimum of 8 and a maximum of 15 characters. It must include at least 1 upper case letter, 1 lower case letter, 1 number, and 1 special character. Click “Save.”

NOTE: Save your username and password for future login. There is a space on page 2 of this manual to write it down. You will need it to set up your Home Base Station and view your Patient Dashboard.

It is recommended that anti-virus and anti-malware software protection be installed to protect computer systems from cyber-attack.

Username

Create Password*

Confirm Password*

* Required

Password Rules

- Must be 8 to 15 characters
- Must include both uppercase and lowercase letters
- Must include at least one number
- Must include at least one special character (i.e., !, @, #, \$)

Clear

4. You will see a screen that looks like the one below. Enter the username and the password you just created. Click “Login.”



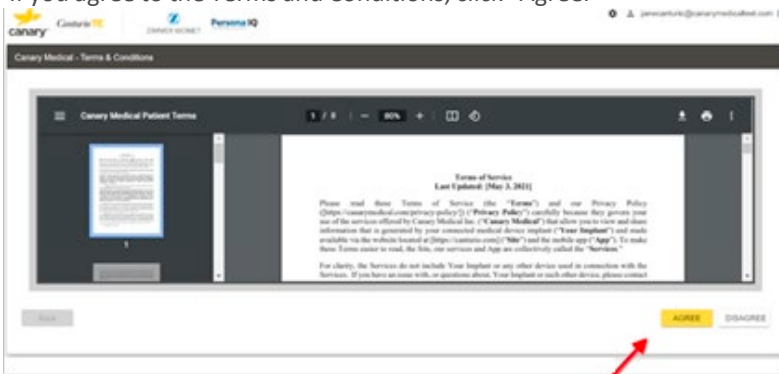
The image shows a login form for the Canary system. On the left is the Canary logo, which consists of a yellow bird icon above the word "canary" in a bold, black, sans-serif font with a trademark symbol. To the right of the logo is a white rounded rectangle containing the login fields. The "Username" field is a text input with a yellow underline, containing the email address "jane.canturio@canarymedicaltest.com". Below it is a "Password" field, which is currently empty. At the bottom left of the form is a link labeled "Forgot Password". At the bottom right is a yellow rectangular button with a black border and the text "Login".

For the best experience, please use Chrome or Edge if you are on Windows, or Safari if you are on MacOS.

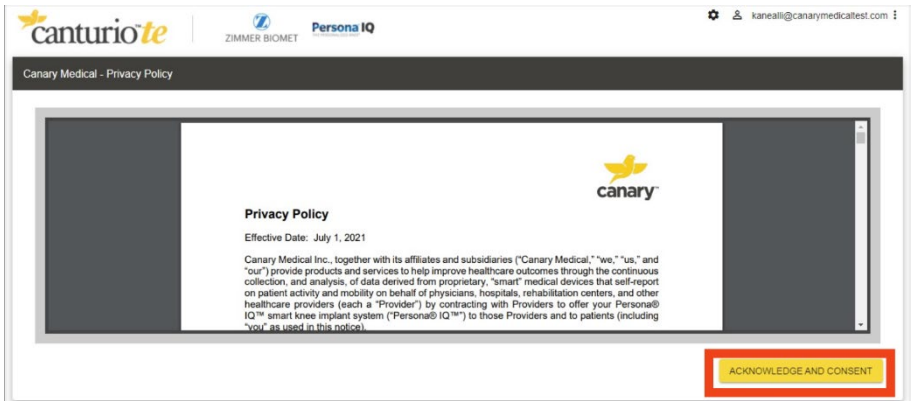
5. You should now be at the Terms and Conditions page, as shown in the screen shot example below. Read the Terms and Conditions for receiving a CTE with CHIRP. To continue with registration, you must Agree to the Terms and Conditions.

You are not required to agree. You can click “Disagree” to stop the account setup process. Your doctor can provide you with a standard knee implant instead of the CTE with CHIRP System. You can also change your mind at any time before having your surgery.

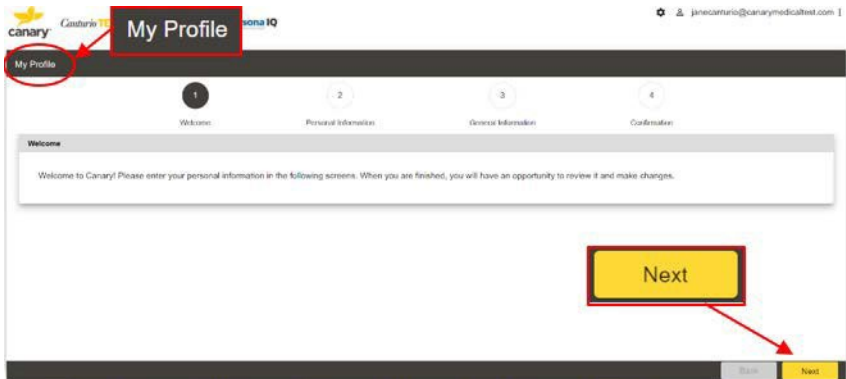
If you agree to the Terms and Conditions, click “Agree.”



6. You should now be at the Global Privacy Policy page, as shown in the screen shot example below. To continue with registration, you must provide your acknowledgment that you have received the Global Privacy Policy (which is also accessible from your patient account after registration). If, after reviewing the Global Privacy Policy, you do not wish to be provided with an implant with the CTE and CHIRP, you may wish to discuss alternatives with your doctor. Please indicate your acknowledgment by clicking “Acknowledge & Consent.”



7. You should now be at the “My Profile” Welcome screen as seen in the screenshot below. Read the information and click “Next.”



8. You should now be at the Personal Information screen. There are 2 areas on this screen where you need to fill in your information, as shown in the screenshot examples below. They are Patient (you) Details and Caregiver Details, which is optional.

NOTE: If you are under 18 years of age, your parent or guardian will need to complete this information.

Each field with a red asterisk next to it is required information that must be added before you can move on to the next screen. Click on each tab and provide the required information. Then click “Save & Next.” If you have a caregiver, select yes to the prompt and enter in their information, otherwise select no and proceed to the next step.

The screenshot shows the 'Personal Information' form in the Persona IQ system. The 'Patient Details' tab is selected and highlighted with a red box. The form contains the following fields:

- First Name* Colton
- Last Name* Strong
- Email* coltonstrong@canarymedicaltest.com
- Middle Name
- DOB* 05-11-1989
- Phone* +1 (999) 409-4904
- Doctor chavis reik
- Mailing Address*
- State/Province* Select state...
- Country* USA

A 'Save & Next' button is highlighted with a red box at the bottom right.

The screenshot shows the 'Personal Information' form in the Persona IQ system. A modal dialog box is displayed over the form asking "Do you have a Caregiver?" with "Yes" and "No" buttons. The 'Patient Details' tab is selected. The form contains the following fields:

- First Name* Colton
- Last Name* Strong
- Email* coltonstrong@canarymedicaltest.com
- Phone* +1 (999) 409-4904
- Doctor chavis reik
- Mailing Address* 123 Mailing Ave
- City* Heraldson

A 'Save & Next' button is highlighted with a red box at the bottom right.

9. You should now be at the General Information screen as shown in the example screen shots below. Fill out the information in the boxes. When you are finished, click “Save & Next.”

General Information

My Profile

1 Welcome 2 Personal Information 3 **General Information** 4 Confirmation

General Information

Weight (and inches)*
Weight (in lbs)*
Sex*

Primary Physician First Name*
Primary Physician Last Name*
Primary Physician Address*
Primary Physician Phone* +1

Save & Next

10. You should now be at the Confirmation screen as shown in the example screen shot below. Click on the arrows on each tab to review all of the information you have input to confirm it is correct. When you are finished, click “Save & Next.”

Confirmation

My Profile

1 Welcome 2 Personal Information 3 General Information 4 **Confirmation**

Confirmation

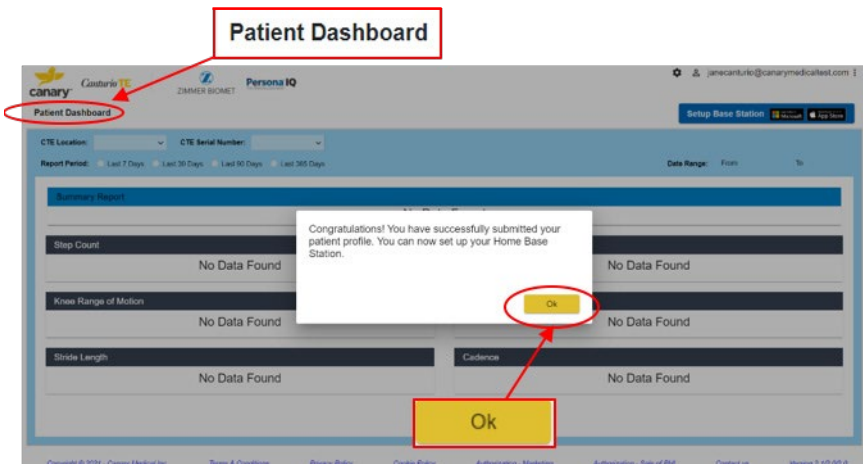
Personal Information
General Information

Click on down arrows to review information.

Save & Next

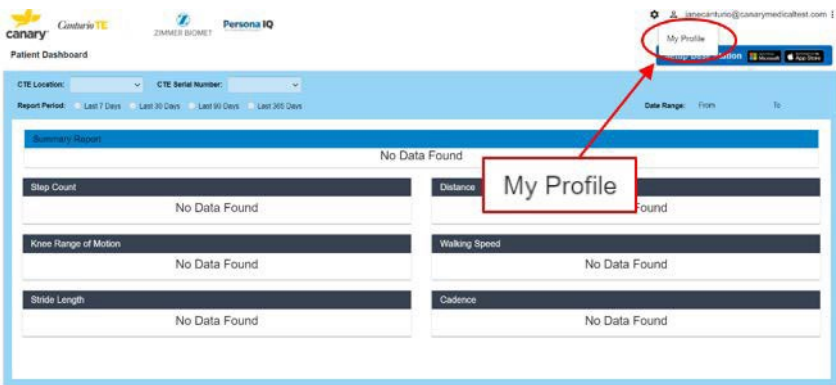
11. You should now be at the Patient Dashboard screen as shown in the examplescreen shot below. This confirms your patient account has successfully been created, and you are ready to set up the Home Base Station in yourhome. Click “Ok.” Your account setup is complete.

Please note: At this point, it is normal for the screen to display “No Data Found” as you have not yet had your surgery. Data will be available on your Patient Dashboard starting on or after day 3 post-surgery.

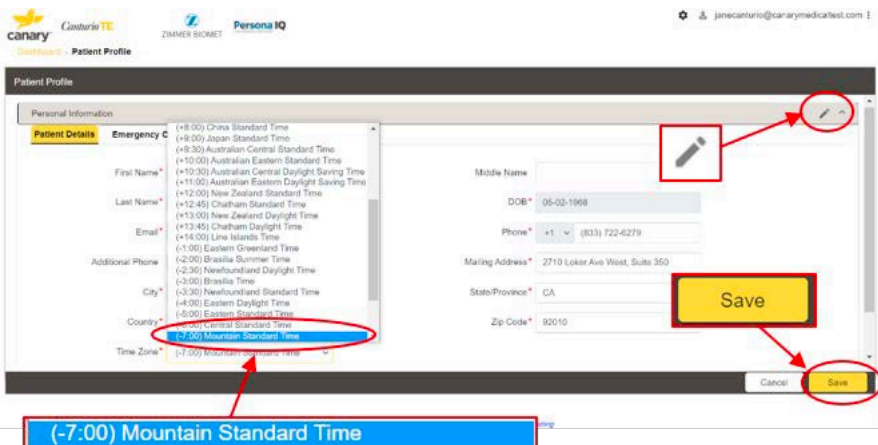


12. If you relocate and change time zones, you can update the old time zone in the “Personal Information” screen.

From the Patient Dashboard, click the “Profile” icon located in the upper-right hand corner of the screen and click “My Profile” as shown in the screenshot example below.



When you are on the “Patient Profile” screen, expand the “Personal Information” section and click on the pencil icon as shown in the screenshot example below. Update the time zone and click “Save.”



Setting Up Your CHIRP® Home Base Station

Canturio™ Tibial Extension (CTE) with CHIRP® System

Make sure your package contains the items shown below. The Home Base Station may be operated between 5° C and 40° C (41-104° F).

You must have a computer with at least one USB connection port as shown below.



You must also have the following:

- Windows 10 or Windows 11
- For Macs: OS 10.15 or higher
- A wireless Internet connection
- Minimum Browser Requirements:
 - Microsoft Edge: 42.17134.1.0
 - Chrome: 71.0.3578.80
- Either a Canary™ Username and Password OR a mymobility® Username and Password
- Your home Wi-Fi Network Name (SSID) and Wi-Fi Password



USB connection port on the side of your computer

1. Use the USB Cable to connect the Home Base Station to your computer as shown below.



NOTE: Apple laptops from 2018 and later do not have USB-A ports. In order to use the USB cable that was provided for use with the Base Station, you need a USB-C adapter.

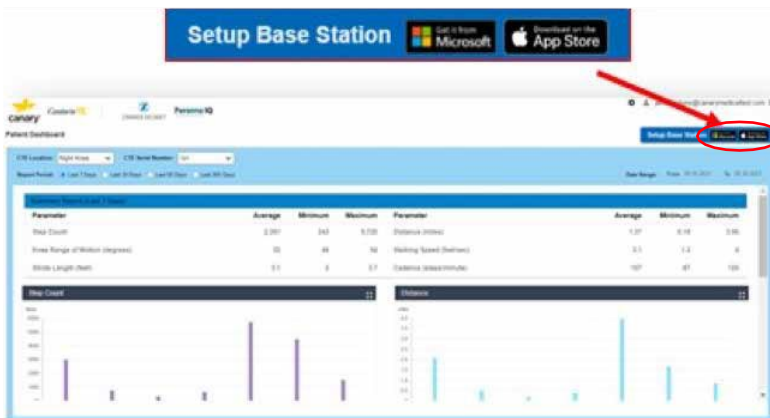
PRE-CAUTION: Do not place your Home Base Station in direct sunlight.

CAUTION: Do not place your Home Base Station directly on or close to a heater which may cause electronics to overheat.

If you do NOT have a Zimmer Biomet mymobility username and password, skip to the “Steps for Users with Canary Medical accounts” section.

2. Steps for users with **mymobility** accounts:
 - a. On your computer, go to the mymobility website:
<https://patient.zbmymobilitysolutions.com/>
 - b. Login in to mymobility using your mymobility username and password.
 - c. Navigate to your homepage task list and select Set Up Persona IQ® Account.
 - d. Complete your Persona IQ® profile tasks.
 - e. Review and complete your Base Station Pre-Check.
 - f. Select the Home Base Station Set Up task.
 - g. Navigate to the Home Base Station Application links to download the software to set up your Home Base Station.
 - h. Click either the Microsoft Store for Windows devices) or App Store (for MacOS devices) and **skip to step 4.**

3. Steps for users with **Canary Medical** accounts:
 - a. On your computer, go to the Canary Medical Website:
www.canarymedical.com
 - b. Select the “Login” button on the top right of the screen.
 - c. The Canary Patient Portal Login screen will appear.
 - d. Log in using your Canary Medical Username and Password.
 - e. Click either the Microsoft Store (for Windows devices) or App Store (for MacOS devices) as circled in the screenshot example below.

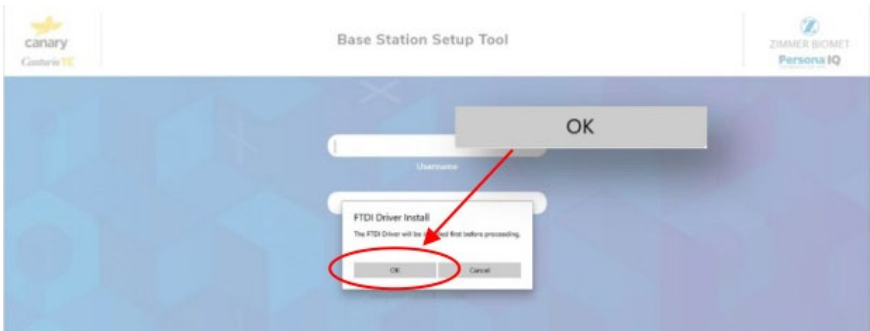


4. Follow installation instructions for your device.

Microsoft Store Users

- a. Clicking on the Microsoft button takes you to the BSST App in the Microsoft Store. Click “Get” to download the free Base Station Setup Tool (BSST) App.
- b. Click “Open Microsoft Store.”
- c. Click “Get” again to begin the download.
- d. Click “Install.”
- e. You will see that the Base Station Setup Tool is downloading on the screen.
- f. When the download is finished, click “Launch.”
- g. The first time you launch the BSST App, you will be asked to install a FTDI driver as shown in the screenshot example below. Click “Ok” to install the driver and “Ok” to make changes to your computer.

NOTE: You need administrative privileges on your computer to allow the BSST App to install the driver.



If the installation fails, please contact SmartKneeSupport@zimmerbiomet.com or call 844-799-8208.

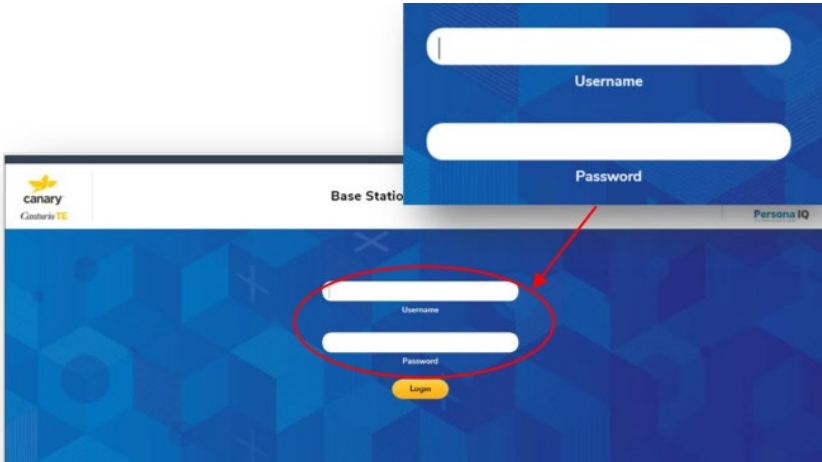
Mac App Store Users

- a. Clicking on the App Store button takes you to the BSST App in the Mac App Store Preview.
- b. If a dialog box to open the Mac App Store does not automatically appear, click on the “View in Mac App Store” link. You will receive a prompt to open the Mac App Store.
- c. Open the Mac App Store.
- d. You will be asked to sign in if you are not already logged in. Enter your Apple username and password to continue the download.
- e. Click “Get” and then click “Install App” to download the free Base Station Setup Tool App.
- f. You will see a screen showing that the Base Station Setup Tool is downloading.
- g. When the download is finished, click “Open.”

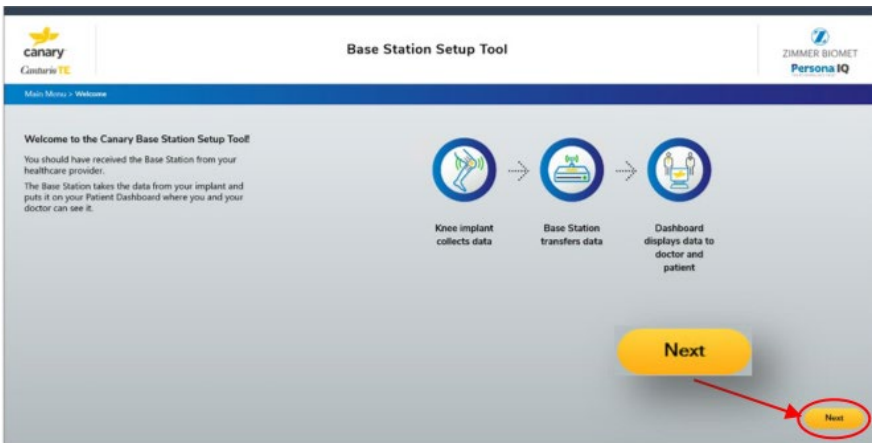
If the installation fails, please contact

SmartKneeSupport@zimmerbiomet.com or **call 844-799-8208**.

5. You will see the Base Station Setup Tool login screen:
 - a. If you are a mymobility user, enter your mymobility username and password.
 - b. If you are a Canary Medical user, enter your Canary username and password.

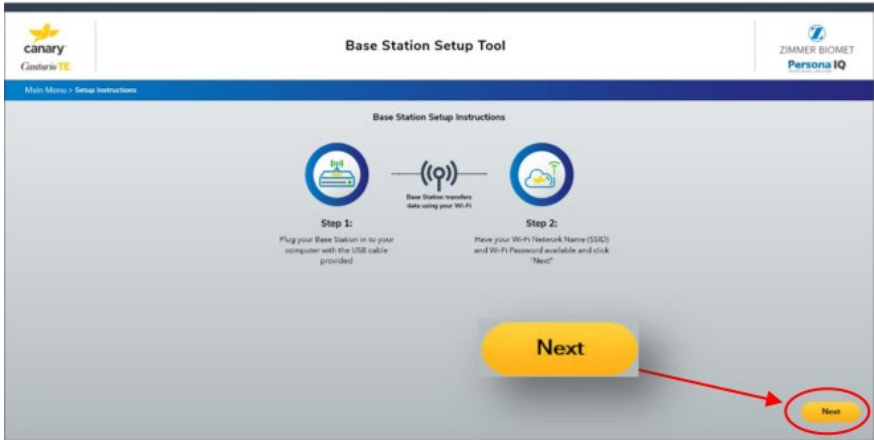


6. You will see the following screen. Read the information and click “Next.”

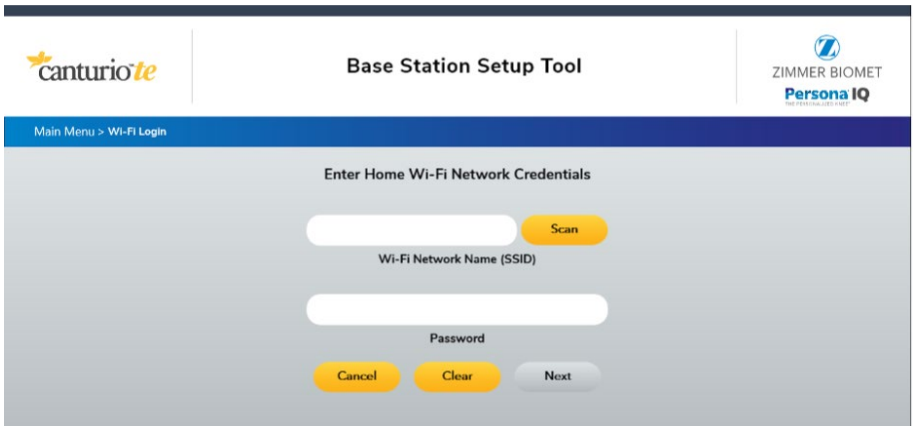


NOTE: If you are not able to see the button to proceed to the following screen, scroll to the bottom of the screen.

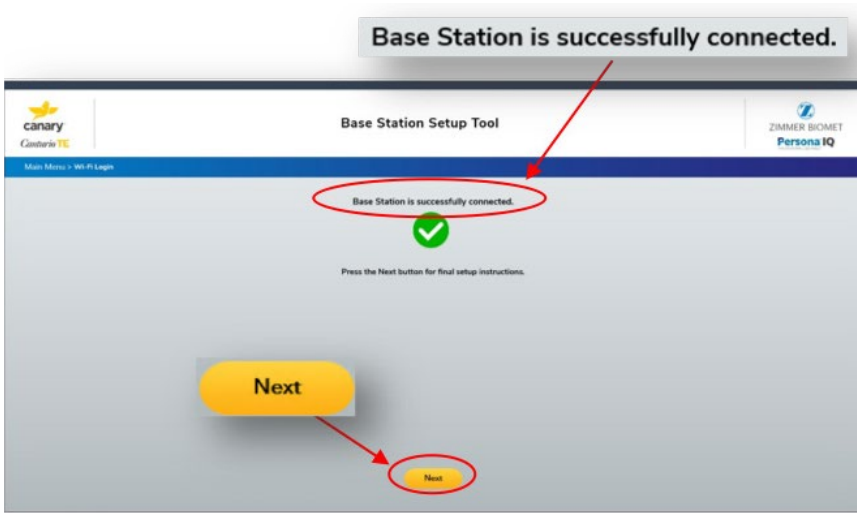
7. You will see the following screen. Read the directions and ensure you have connected your equipment correctly. Click “Next.”



8. Enter your home Wi-Fi Network Name (SSID) and Wi-Fi Password and click “Next” as shown in the screenshot example below. Alternatively, you may click the “Scan” button to choose from a list of nearby Wi-Fi networks detected by your system. If you choose to do so and select a network from the list, the SSID box will be pre-filled for you, and you can enter the Wi-Fi Password and proceed.



9. When you see the screen below, your Base Station is successfully connected. Click “Next.”

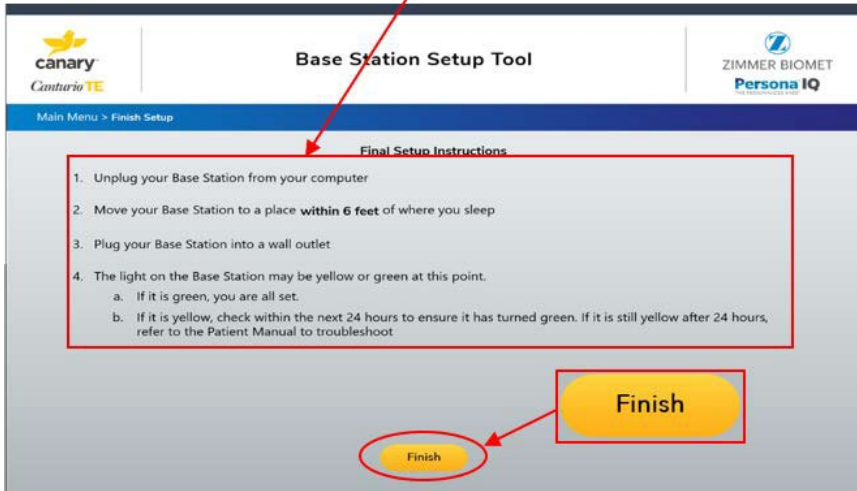


10. When you see the “Final Setup Instructions” as shown in the screenshot example below, disconnect the USB end of the Cable from your computer. Leave the other end plugged into the Base Station.

Follow the instructions on the screen. If you need help, the pictures on the following pages show you how to make the connections described on the screen.

When you have completed all the steps, click “Finish” as shown on the screenshot example below. You’re all set!

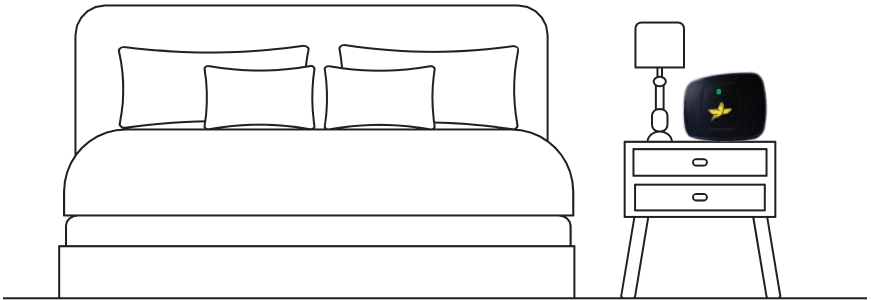
1. Unplug your Base Station from your computer
2. Move your Base Station to a place **within 6 feet** of where you sleep
3. Plug your Base Station into a wall outlet
4. The light on the Base Station may be yellow or green at this point.
 - a. If it is green, you are all set.
 - b. If it is yellow, check within the next 24 hours to ensure it has turned green. If it is still yellow after 24 hours, refer to the Patient Manual to troubleshoot.



This photo shows how to plug the USB end of the Cable into the Wall Plug Adapter.



Move the Home Base Station, connected to Cable and Wall Plug Adaptor, to a location **within 6 feet of your sleeping area** and **plug it into a wall outlet**.



The light on the front of the Home Base Station will be yellow as it establishes the connection with your Wi-Fi and the Canary Medical website and will turn to a solid green when it is successfully connected.

Operating Your Home Base Station

Make sure your Home Base Station is correctly located in its permanent location within 6 feet of your typical sleep location, plugged in to a wall outlet, and connected to your home Internet system. That's all you need to do.

Your CHIRP System with Home Base Station will operate automatically without further input from you.

After your surgery, your system will collect, store, and transmit information from your implant. Your doctor will be able to view information about your activity levels, and so will you. Just go to your Patient Dashboard on the Canary Medical website.

NOTE: If you change your wireless Internet connection, for example, if you move or change Internet providers, you will need to re-do the Base Station Setup steps in this section.

Your Patient Dashboard

Your new knee implant with CHIRP® System allows your doctor to monitor your activity level after your surgery. You can use your computer to go on the internet and view your Patient Dashboard. Just log in to your account with the username and password you set up earlier, and you will see your Patient Dashboard.

You will be able to see the following information:

- The number of steps you take (your Step Count)
- The distance you have walked (your Distance)
- How much your knee bends and straightens (your Range of Motion)
- How fast you walk (your Walking Speed)
- The amount of distance you cover between the time when one foot hits the ground and then the same foot hits the ground again (your Stride length)
- How many steps you take per minute (your Cadence)

The CHIRP system is not intended to provide real-time data like a smart watch or your smart phone. Rather, it collects information over the course of a day and analyzes it while you are asleep. The following day, you and your doctor will be able to see the information on your dashboards.

Your CTE implant has the ability to store 30 days of data. Therefore, if your Home Base Station connection is temporarily lost or you are traveling for less than 30 days without a Home Base Station, the full amount of data will be uploaded once a connection is made to the Home Base Station.

If there is no connection for periods greater than 30 days, new data will overwrite the oldest data until a connection to your Home Base Station and the Canary Cloud is made.

Your CTE implant has been programmed to collect data according to the following schedule:

Time Period	Data Collection
Day of surgery and day after surgery	No data collection
Day 2 to Day 365	Data is collected daily
Year 2	36 consecutive days/quarter
Years 3 and beyond	36 consecutive days starting on the anniversary of your surgery date

When the CTE is not collecting data, it is in a low power mode to conserve battery power. When viewing your data, if no values are present during a particular day or period of time, it simply means during this period the CTE was not collecting data per its program.


The picture on the following page shows an example view of a Patient Dashboard.

Setup Base Station  

Report Period: Last 7 Days Last 30 Days Last 90 Days Last 365 Days

CTE Location: Right Knee **CTE Serial Number:** 141

Date Range:

canturio  Persona IQ

john.canturio@sonarymedical.com




Summary Report - All 7 Days

Parameter	Average	Minimum	Maximum	Parameter	Average	Minimum	Maximum
Step Count	1,294	343	3,008	Distance (miles)	0.71	0.19	2.08
Knee Range of Motion (°)	94	84	104	Walking Speed (mph)	3.0	3.3	4
Stride Length (feet)	3.8	3.8	3.8	Cadence (steps/min)	119	106	135

Step Count **Distance** **Knee Range of Motion** **Walking Speed** **Stride Length** **Cadence**



Patient Dashboard Legend

Settings	Click on the  icon to change your password
My Profile	Click on the  icon to edit your Personal or General Information
Setup Base Station	Click on either the Microsoft or App Store button to download the Base Station Setup Tool (BSST)
CTE Location	Displays the location of your CTE Implant. If you had a bi-lateral surgery, you can choose to see the data from either the left or right knee from this drop-down list
CTE Serial Number	Displays the serial number of your CTE Implant. If you have multiple surgeries on one knee, you can select the different CTE serial numbers from this drop-down list
Report Period	You can choose to see your data from the last 7 days, the last 30 days, the last 90 days or the last 365 days
Date Range	Reflects the range of days for which the data is shown
Parameter: Average	Displays the average measurement for the selected report period
Parameter: Minimum	Displays the lowest measurement within the selected report period
Parameter: Maximum	Displays the highest measurement within the selected report period
Step Count	Displays the number of steps taken
Distance	Displays the distance traveled (in miles)
Knee Range of Motion	Displays the angle your knee moves between flexion (bending) and extension (straightening)
Walking Speed	Displays how fast you walk (feet per second)
Stride Length	Displays the length of your step between one foot hitting the ground to the same foot hitting the ground again
Cadence	Displays the steps taken per minute
Enlarge	Click the  icon to enlarge the chart

Maintaining Your CTE with CHIRP® System

Cleaning

Once a week, wipe the surface of the Base Station unit with a dry, soft cotton cloth. Do not use wet cloths or paper towels and do not immerse the Base Station unit in water.



Degree of protection (applied part) against electric shock:
The entire device is an applied part and is classified as of type BF (see symbol to the left) per IEC 60601-1.

NOTE: The Base Station Unit and Accessories are resilient to dust, lint, and light (including sunlight). However, lint or dust may get into the USB receptables or the receptacles may become degraded and interfere with power to or communications with the Base Station or Accessories. Children, pets, and pests may have similar effects on the USB receptacles and similar degraded performance of Base Station or Accessories. Do not attempt to clean or repair the USB receptacles. Instead contact Canary Medical for a replacement.

Storing

There are no special storage instructions for the Base Station. The Base Station should remain plugged in within 6 feet of where you typically sleep so it can regularly receive activity information from your implant.

What to do if Your CHIRP System Equipment Stops Working

If your equipment shows errors or even changes in performance that you cannot fix by using the information in this manual, or if it stops working completely, contact Canary Medical at the phone number below:

1-833-692-2627

How to Dispose of the CHIRP System Equipment

Do not dispose of the Base Station in household trash. Call Canary Medical at the phone number below for instructions: **1-833-692-2627**

Or contact your local authorities to determine proper method of disposal.

Service Life

The Base Station unit and Accessories are intended to last for 3-5 years and can be replaced in case they become non-operational.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure 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 the other wireless device away from each other.

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 100kHz 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)}	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% UT; 0,5 cycle ^{g)} At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° ^{q)} 0% UT; 1 cycle and 70% UT; 25/30 cycles ^{h)} Single phase: at 0°	

Phenomenon	Basic EMC Standard	Immunity Test Levels	
		Professional Healthcare Facility Environment	Home Healthcare Environment
Voltage interruptions ^{f) i) o) r)}	IEC 61000-4-11	0% U _T ; 250/300 cycle ^{h)} Single phase: at 0°	

- a) This test applies only to output lines intended to connect directly to outdoor cables.
- b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.
- 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 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
- f) be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.
- g) Capacitive coupling shall be used.
- h) If the frequency stepping skips over an 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.
- i) r.m.s., before modulation is applied.
- j) The ISM (industrial, scientific and medical) bands between 150 kHz and 80
- k) 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
- l) to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Electromagnetic Emissions

canturio™ te is intended for use in the electro-magnetic environment specified in the next table. Ensure that the transmitter is used in such an environment.

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 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.

US Federal Communications Commission (FCC)

For FCC compliance information, please go to <https://canarymedical.com/compliance-fcc>.

Troubleshooting

The table below lists some problems you might have with your CHIRP System and suggested actions you can take to try to fix the problem. If you have a problem with the system that is not listed here or that cannot be fixed with the information provided, call your doctor or Canary Medical.

If the problem you are experiencing is with your health (such as pain or limited mobility) and not with the operation of your CHIRP System, call your doctor.

If you are experiencing a health emergency, call 911.

NOTE: Do not attempt to modify or service the Base Station since this may damage the device or result in unsafe conditions.

Problem	Action
The light on the Base Station is not lit.	Make sure the USB Power and Data Cable is connected to the Base Station and Wall Plug Adapter. Make sure the Base Station is plugged into the wall outlet.
I can't reach the Canary Medical website.	Check your home internet and make sure you are connected to the internet. If connected and still can't reach the Canary Medical website, try again later and/or contact Canary Medical at: 1-833-692-2627 or support@canarymedical.com .
I can't log in to my Patient Account.	Check your username and password.
I can't see my Patient Dashboard information.	You will only see information on your Patient Dashboard beginning 3 days after your surgery. If your information is still not on your Patient Dashboard at this timepoint, check your Base Station to make sure the light is solid green. If the light on your Base Station is green, check your Patient Dashboard information again in 24 hours.
The light on the Base Station is solid red.	Unplug the Base Station, wait 5 seconds, and plug it back in. If the light remains solid red, contact Canary Medical at: 1-833-692-2627 or support@canarymedical.com .
The light on the Base Station is solid yellow.	Check your home Wi-Fi signal to make sure it is operating. This can be done by checking your smart phone's Wi-Fi signal in your bedroom next to your Home Base Station. Wait 24 hours and recheck the light on the Home Base Station. If it is still solid yellow, reconnect the Home Base Station to your computer, and go through the Base Station Setup Process starting on page 24 of this manual.
The light on the Base Station is blinking yellow.	Make sure your home internet is working. Reset your Wi-Fi router if needed. Wait 24 hours and re-check the light on the Home Base Station. If it is still blinking yellow, and/or contact Canary Medical at: 1-833-692-2627 or support@canarymedical.com .

Frequently Asked Questions (FAQs)

How do I know my CHIRP System is connected to the internet?

Check to make sure the green light on the Base Station unit is lit. This shows that your system is connected to the Internet.

How do I know my CTE system is transmitting?

Log in to your Patient Dashboard after surgery. If the information being displayed is from the past 24 hours, you can be sure your CTE is transmitting.

How long will my CHIRP system collect information from my implant?

At least ten years.

What if my internet connection goes down or is interrupted?

Ensure your internet is re-established and working properly. Check to make sure the green light on the Base Station unit is lit. This shows that your system is connected to the internet.

What if I get a new computer?

A new computer will not affect your CTE with CHIRP System. Navigate to the Canary Medical website and log in to your Patient Dashboard with your Username and Password.

Will my system stop working if I fall or injure the knee that has the implant?

After the fall or injury, wait 24 hours and log in to your Patient Dashboard. If the information being displayed is from the past 24 hours, you can be sure your CTE is still working properly. If you are concerned or in pain, call your doctor.

How do I get help if I have questions about my implant?

If you have questions about your TKA surgery or the knee that has the implant, call your doctor.

How do I get help if I have questions about my HomeBase Station?

Contact Canary Medical.

Who can view my personal health information that is transmitted by the implant?

Your doctor and their qualified staff can view your personal health information transmitted by the implant. You can also view your information on your Patient Dashboard, located on the Canary Medical website. For your security, don't share your username and password with anyone you don't want to be able to view your personal health information.

Is my health information secure?

Yes, the information from your implant is transmitted over a secure and encrypted connection and stored securely in the Canary Medical database. For additional data security, we recommend that you purchase and install software virus and malware protection on your personal computer if you don't already have it.

Caring for Your Health After Your TKA

After your TKA procedure, it's important to continue to take care of yourself. Do the following to be as healthy as possible and give yourself the best chance for a successful recovery:

- Follow your post-surgery instructions about diet, medications, and exercise.
- Keep a regular schedule of rehabilitation exercises as directed by your surgeon or your doctor.
- Make sure you keep up with all of your follow-up appointments with your surgeon or your doctor.
- Get regular general health checkups.
- Before having any medical or dental tests or treatments, tell your care providers that you have a Canary implant.
- Some medical procedures use medical equipment that introduces electrical currents into your body. These procedures may not be safe with the Canary Medical CTE implant. After your surgery, make sure you carry your implant card. Inform your health care provider that you have a Canary Medical CTE implant before any medical procedures using medical equipment.

Can I travel with my CTE and CHIRP system?

You can travel with your CTE and CHIRP System.

Metal Detectors and Security Systems

Many knee implants will set off the metal detector at airports and other secure buildings. Tell the security agent that you have a knee implant before passing through the metal detector. It's also a good idea to carry your implant card with you.

Your Home Base Station

Your CTE stores thirty days of information within the implant itself, so you don't have to worry about taking your Home Base Station with you on most trips. When you get home, the CTE and Home Base Station will transmit the stored information to your doctor and your Patient Dashboard.

If you are going to be traveling for more than thirty days, the implant will keep collecting information. However, it will start to overwrite information that is more than thirty days old. Make a note of your travel dates, so you will know why your Patient Dashboard will not show information during that time period.








If you spend part of the year away from home, for instance, if you have a second summer or winter home, simply take your Home Base Station and accessories with you to your new location. Repeat the setup steps in this manual and you are all set. Your CTE implant will transmit as usual.










What if I Move?





If you move, just take your Home Base Station and accessories with you to your new home. Repeat the Base Station setup steps in this manual and you are all set. Your CTE implant will transmit as usual.

Symbols

The table below shows symbols that you may see in this document, on your device, or on the device packaging, and provides the symbols' meanings.

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
	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
	The unique serial number assigned to the device by the manufacturer	ISO 7000 — 2498 Graphical symbols for use on equipment — Registered symbols	Serial Number
	Computer-to-computer exchange of business documents in standardized formats		Electronic Data Interchange
	To indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 7000-0434A Graphical symbols — Safety colors and safety signs — Registered safety signs	Caution
	Directs the user to read the instructions for use	ISO 7010-M002 Graphical symbols — Safety colors and 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	Refer to instruction manual/booklet

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
	For prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.	
	To identify a type BF applied part complying with IEC 60601-1	ISO 7000-5333 Graphical symbols for use on equipment — Registered symbols	Type BF applied part
	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, labeling 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, labeling and information to be supplied	
	Transport and storage temperature limit	ISO 14708-1 clause 9.11	Temperature limit
	Transport and storage humidity limit ISO 7000-2620	ISO 14708-1 clause 9.11	Humidity limitation
	Transport and storage atmospheric limit ISO 7000-2621	ISO 14708-1 clause 9.11	Atmospheric pressure limitation
	To identify electrical equipment designed primarily for indoor use	ISO 7000-5957 Graphical symbols for use on equipment — Registered symbols	For indoor use only
	Non-ionizing radiation includes RF ISO 7000-5140	IEC 60601-1-2:2007, Clause 5.1.1	Non-ionizing electromagnetic radiation

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
	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
	Indicates the # of unit per package		Quantity
	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
			Health Industry Bar Code (HIBC)



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

Jane Canturio is an imaginary patient with a fabricated surname.

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Not all patients are candidates for this product and/or procedure. Only a medical professional can determine the treatment appropriate for your specific condition. Appropriate post-operative activities and restrictions will differ from patient to patient. Talk to your surgeon about whether joint replacement is right for you and the risks of the procedure, including the risk of implant wear, infection, loosening, breakage or failure, any of which could require additional surgery.

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