



Software and Services Analytics

Instructions for Use



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1. Overview of Canary™ Recovery Curves™

Before using Canary Recovery Curves, carefully read all instructions for use.

Canary™ Recovery Curves™ analytics is an accessory and an optional software module for use with the Canturio™ Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System. For additional information on the CTE with CHIRP System, refer to the Physician Instructions for Use (K01-CTE-300004).

Canary Recovery Curves software provides health care professionals (HCPs) with additional physiological insights when managing a patient's total knee arthroplasty (TKA) post-surgical care. Canary Recovery Curves obtain kinematic data from the CTE with CHIRP System and provide aggregation and visualization of patient population data to analyze patient recovery progress and direction of outcome.

2. Terms and Acronyms

Term/Acronym	Meaning
CDMP	Cloud Data Management Platform
CHIRP	Canary Health Implanted Reporting Processor
CTE	Canturio™ Tibial Extension
HCP	Health Care Professional
HIPAA	Health Insurance Portability and Accountability Act of 1996
IFU	Instructions for Use
ROM	Range of Motion
TKA	Total Knee Arthroplasty

3. Device System Description

Canary™ Recovery Curves™ analytics provides aggregate population data that offers health care professionals (HCPs) with additional physiological insights when managing a patient's total knee arthroplasty (TKA) post-surgical care. When used with the Canturio™ Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System, the software aggregates gait parameter data obtained from patients with the CTE implant to create Canary Recovery Curves.

Canary Recovery Curves provided by the software are a set of patient-population distribution curves aggregated from gait parameter data captured by patients with the CTE implant and illustrate the average patterns of gait parameters during patient recovery. The percentile bands within the Canary Recovery Curves delineate proportions of the population whose gait metric data fall within the percentile range. When viewing Canary Recovery Curves for a given patient, the data points are shown as weekly averages.

Canary Recovery Curves are available for the following Canary Medical Gait Parameters:

- Qualified Step Count
- Distance (kilometers)
- Tibia ROM (degrees)
- Walking Speed (meters/second)
- Functional Knee ROM (degrees)
- Cadence (steps/minute)
- Stride Length (meters)

Details of the Canary Medical Gait Parameters Data characteristics can be found in Table 5 of the Physician Instructions for Use (K01-CTE-300004).

Canary Recovery Curves support a deeper and broader analysis of a patient's recovery when comparing a patient's gait parameters to the gait parameters of the total CTE population or specific cohorts based on selected patient demographics (e.g. age). The backdrop of aggregated data provides context for the gait parameters and can help to observe a patient's progress between in-person visits.

Canary Recovery Curves can only be accessed through the CTE with CHIRP Physician Dashboard on the Canary Medical website (www.canarymedical.com) by preference and enabling the accessory software on a Patient Chart.

4. Intended Use

Canary™ Recovery Curves™ analytics provides health care professionals (HCPs) with additional aggregate population data when managing a patient's total knee arthroplasty (TKA) post-surgical care. HCPs can filter or select options for additional views based on patient demographics (e.g. age), to analyze trends and outcomes. Canary Recovery Curves analytics allows HCPs to view aggregate patient population data to analyze patient recovery progress and direction of outcome.

Canary Recovery Curves analytics does not control the function or parameters of the Canturio™ Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System and is not intended for active patient monitoring.

5. Directions for Use

5.1 Enabling Canary™ Recovery Curves™

After setting up your HCP account on the Canary™ Cloud Data Management Platform (CDMP) (refer to K01-CTE-300004 - Physician IFU), follow the steps and screenshots below to access Canary Recovery Curves analytics.

When you are viewing a Patient Chart, you will see a button to enable Canary Recovery Curves on the user interface as displayed in the screenshot example on the following page.

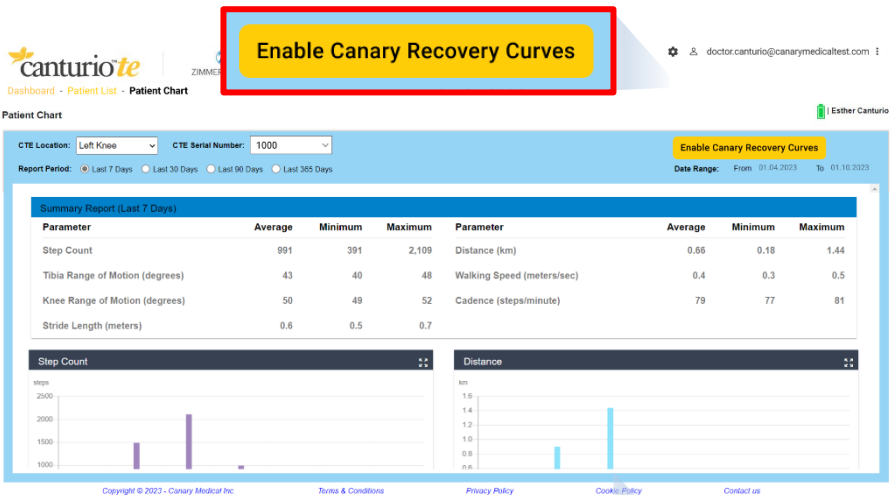


Figure 1

1. Click on the button to enable Canary Recovery Curves analytics view. This will open a module displaying the Canary Disclaimer. You must accept the Canary Disclaimer and acknowledge and consent to using the Canary Recovery Curves application in order to proceed to the Canary Recovery Curves view. If you do not agree, you will be taken back to the

CDMP. See below for an example of the Canary Disclaimer.

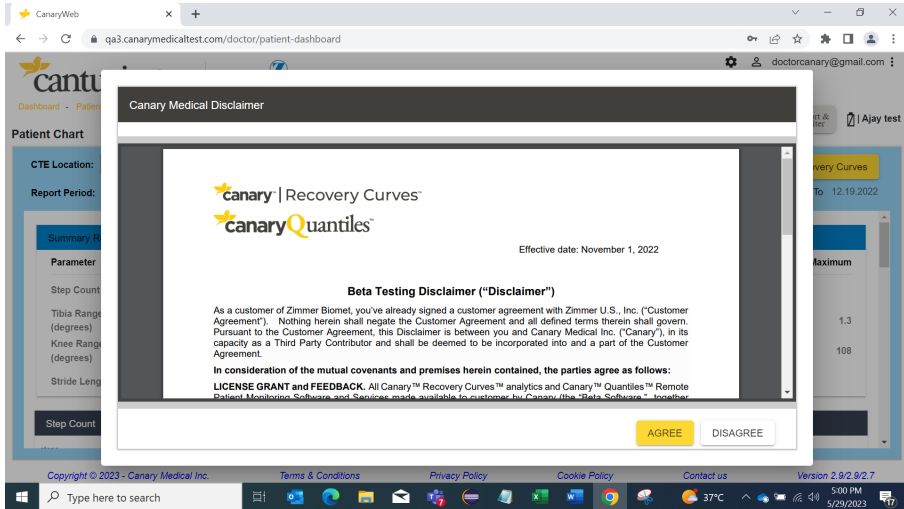


Figure 2

Accepting the Canary Disclaimer and acknowledging and consenting to using the Canary Recovery Curves application takes you to the Canary Recovery Curves view.

2. To return to the CDMP from Canary Recovery Curves, click on the breadcrumb as shown in the image below. The link will take you to the Patient List on the CDMP.

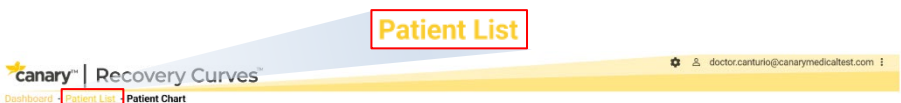


Figure 3

After enabling Canary Recovery Curves once, you will no longer see the button to enable Canary Recovery Curves and will not have to accept the disclaimer again. Navigating to the Patient Chart will now show a Recovery Curves dropdown with None selected. Figure 4 displays this view on the CDMP.

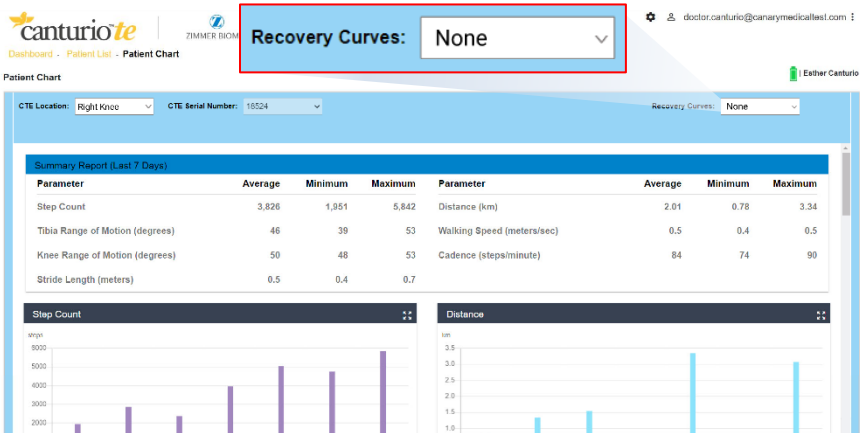


Figure 4

3. To access Canary Recovery Curves again, click on the Recovery Curves dropdown and select an available Canary Recovery Curves cohort. See the example image below.

Patient Chart



Figure 5

5.2 Canary™ Recovery Curves™

For every gait parameter captured by the CTE, Canary Recovery Curves analytics will display aggregate patient data in percentile groups which are bound by the following percentiles: 5th, 10th, 25th, 50th, 75th, 90th, and 95th. Only the 5th, 50th and 95th percentiles are labeled on the graphs. A percentile score indicates what percentage of patients have a gait parameter value below the scored patient. For example, if a patient has a percentile score of 90%, it means the patient has a gait parameter value that is larger than 90% of the patients in the TKA cohort.

The x-axis of the Canary Recovery Curves displays data as Weeks Post Surgery. Patient data are laid over the Canary Recovery Curves and shown as weekly timepoints. These data points are 7-day averages of the patient’s gait parameters post TKA surgery. See an example in the image on the following page.

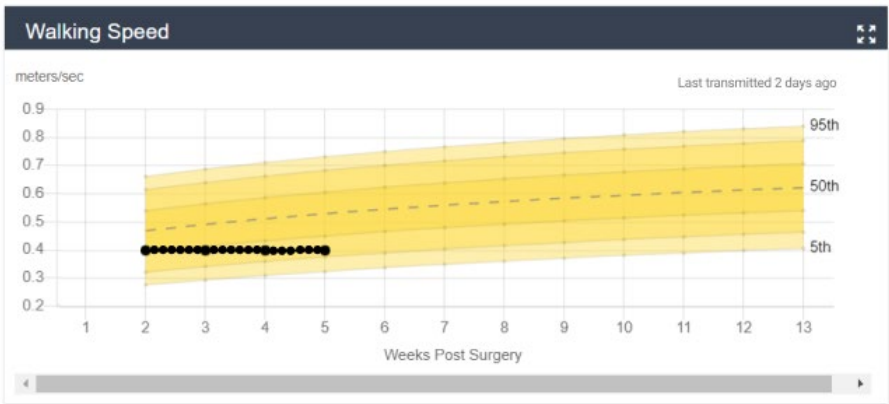


Figure 6

The default Canary Recovery Curves cohort that will be displayed is the All Patients cohort. Clicking on the drop-down menu provides an option to select another available cohort as displayed in the example image below.

canary™ | Recovery Curves™

doctor.canturio@canarymedicaltest.com

Dashboard - Patient List - Patient Chart

Canary Quantiles | Sort & Filter | Esther Canturio

Patient Chart

CTE Location: Right Knee | CTE Serial Number: 1000 | Estimated Date of Surgery: 03.13.2021

Age at Surgery: 56 | Current Age: 58 | BMI: 19.33 | Sex: Female

Recovery Curves: All Patients

None | All Patients | Female >=65 (65 years old and older) | Male <=64 (64 years old and younger) | Male >=65 (65 years old and older) | Female <=64 (64 years old and younger)

Parameter	Average	Minimum	Maximum	Parameter	um
Qualified Step Count	899	351	2,109	Walking Speed (meters/sec)	0.4 0.3 0.5
Functional Knee Range of Motion (degrees)	50	49	52	Tibia Range of Motion (degrees)	43 40 48
Stride Length (meters)	0.6	0.5	0.7	Cadence (steps/minute)	78 76 81
Distance (km)	0.58	0.18	1.44		

Qualified Step Count | Walking Speed

- None
- All Patients
- Female >=65 (65 years old and older)
- Male <=64 (64 years old and younger)
- Male >=65 (65 years old and older)
- Female <=64 (64 years old and younger)

Hovering over specific areas on the graph will display tooltips that provide timepoints as well as aggregate or average gait parameter values. See an example in the image below.

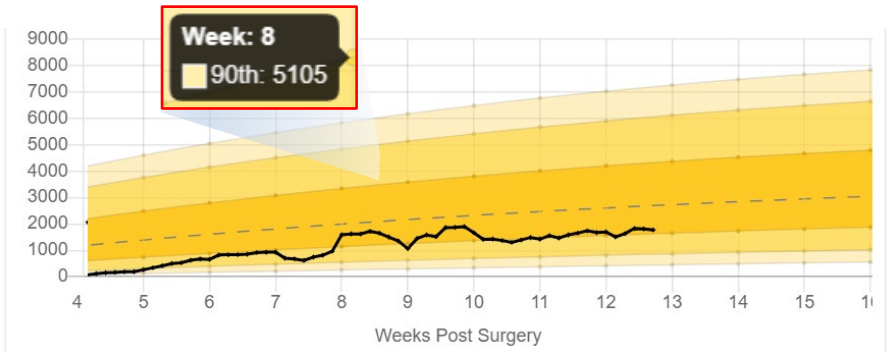


Figure 9

6. General Warnings and Precautions

Canary™ Recovery Curves™ analytics is intended for ongoing patient care management and is not intended for instant communication in emergency situations.

It is not intended for active patient monitoring.

7. Compatibility with Other Devices

Canary™ Recovery Curves™ analytics is compatible with a range of computing devices and systems. Table 1 below lists the compatible device types and operating systems, and minimum specifications that will be required in order for data from the CTE and Canary Recovery Curves to be accessible from the Canary Medical website to health care providers.

Table 1. Compatible Device Types and Operating Systems

Minimum supported resolution	1024 x 768
Supported browsers and minimum versions	Microsoft Edge / Google Chrome version 42.17134.1.0
Minimum operating environment for the PC that runs the Base Station Setup Tool (patient PC)	Windows 10 or higher version 71.0.3578.80

8. Data Security and Privacy

Canary™ Recovery Curves™ analytics can only be viewed and accessed by an HCP with a unique user account via the Physician Dashboard on the Canary™ Cloud Data Management Platform which was designed to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). For additional information on data security and privacy for the CTE with CHIRP, refer to Section 16 – Data Security and Patient Privacy of the physician instructions for use (K01-CTE-300004).



To learn more about the
Canary™ Recovery Curves™,
email support@canarymedical.com or
call **833-722-6279**.

Esther Canturio is an imaginary patient with a fabricated surname.

Doctor Canturio is an imaginary doctor with a fabricated name.

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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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