CanarE™ System
Instructions for Use

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

How to Contact Canary Medical

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1. Overview

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

The CanarE System includes three components as shown in Figure 1 below:

- CanarE (wearable device) with Straps (not shown)
- CanarE Charger
- Clinic Cart

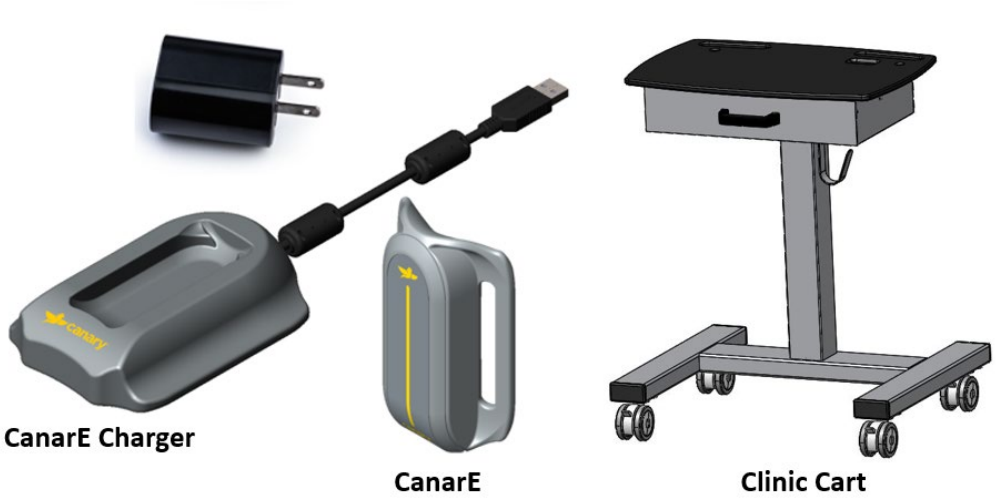


Figure 1. CanarE System Components

It is intended to be used in conjunction with the Clinic Base Station System, specifically with the following subsystems:

- Clinic Base Station
- Clinic PC and Application

The CanarE System is intended to provide objective kinematic data on a patient's knee function before or after total knee arthroplasty (TKA). This system produces kinematic data intended as an adjunct to the standard of care as directed by the physician. It also collects the patient kinematic data from its internal motion sensors (identical to the CTE implant). When queried by the Clinic Base Station, it transmits the patient kinematic data to the Clinic Base Station. The Clinic Base Station, in turn, uploads the data to the Clinic Laptop when connected. Next, that data is uploaded to the Canary Cloud Data Management Platform ("Cloud"). Figure 2 provides a schematic overview of the system's components and interfaces.

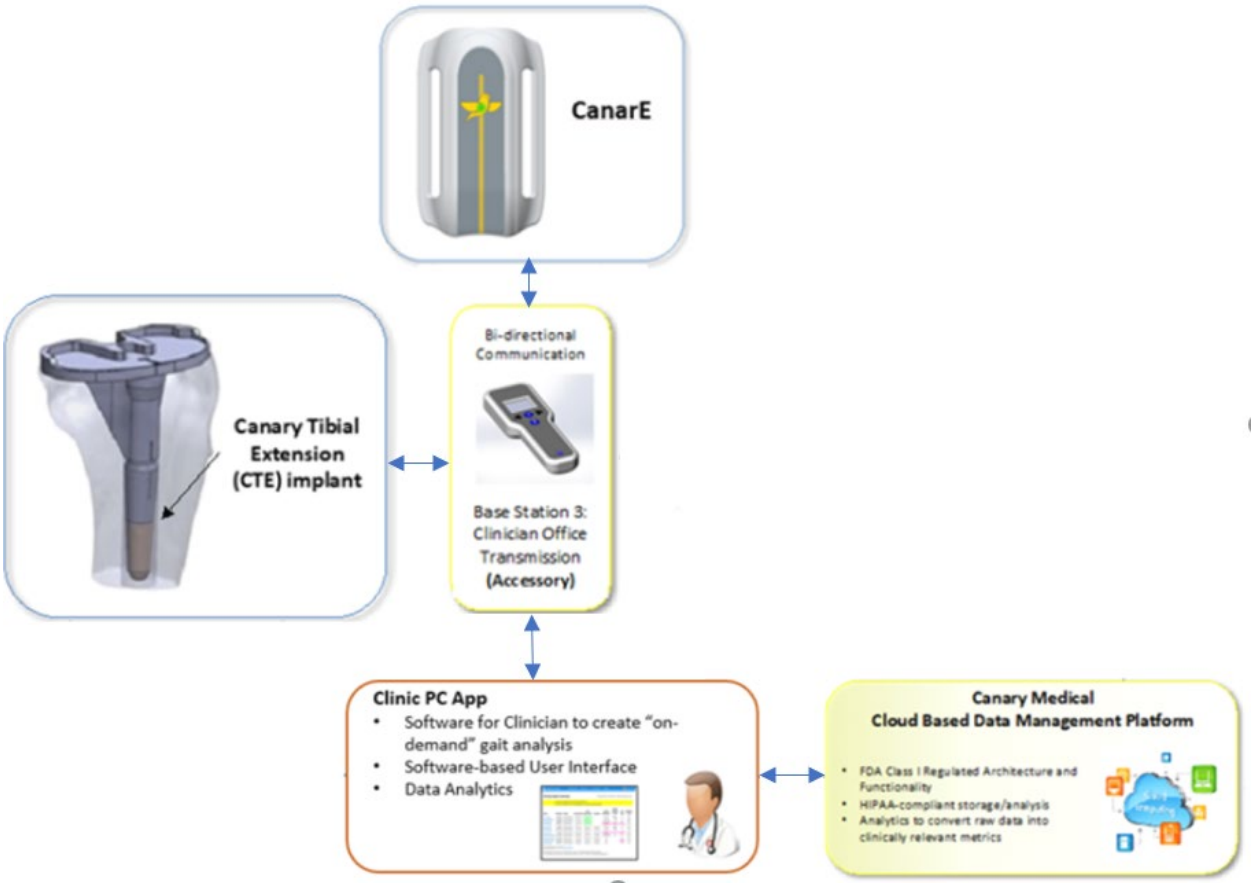


Figure 2: System Component Interfaces

The Clinic Cart is an accessory to use, store, charge, and transport the components of the Clinic Base Station System and CanarE System.

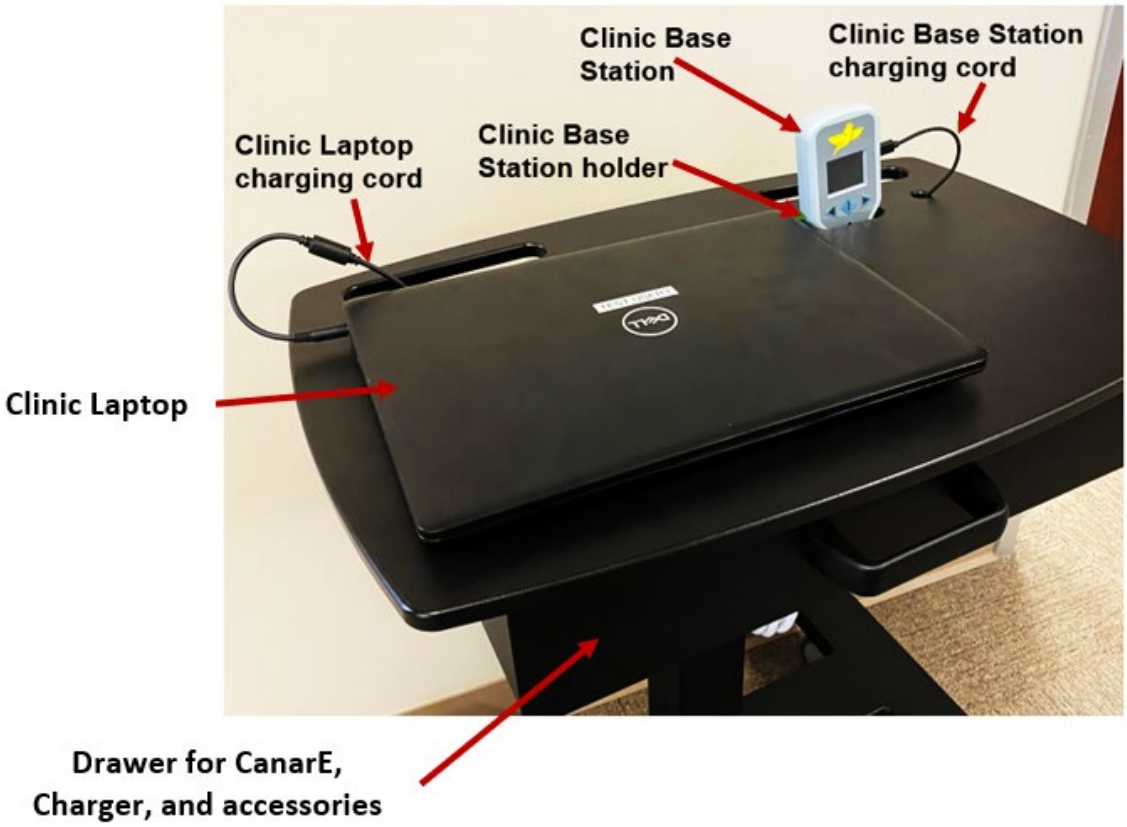


Figure 3: Clinic Cart

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
K02-CBS-300003	Clinic Base Station System – IFU
K03-CRT-800000	Clinic Cart – Assembly Document

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 and after a patient's TKA surgical procedure.
CDMP ("Cloud")	Canary Cloud 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
CHIRP™	Canary Health Implanted Reporting Processor
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
PC	Personal Computer
ROM	Range of Motion
RTU	Ready-To-Use

Term	Definition
SW	Software
TKA	Total Knee Arthroplasty
USB	Universal Serial Bus

4. Intended Use

The CanarE is intended as an accessory for use with the Clinic Base Station System to provide objective kinematic data from an external wearable device to assist the clinician before or after a patient's TKA surgical procedure. The kinematic data is intended as an adjunct to standard of care and physiological parameter measurement tools applied or used by the physician during patient monitoring and treatment.

The CanarE is not intended for diagnostic or therapeutic uses or in conjunction with rehabilitation or therapeutic exercise.

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 CanarE System.

WARNING: Plug CanarE 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 CanarE and accessories or use them adjacent to other electrical equipment.

WARNING: Do not immerse the CanarE or accessories in water. Electric shock could result.

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

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

5.3. Precautions

CAUTION: Make sure that the system components are not visibly damaged prior to use.

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

CAUTION: Only use cleaning or disinfection 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 CanarE 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) with the CanarE.

6. Packaging Content

The CanarE System package contains the following items:

- CanarE (wearable device)
- CanarE Charger with power cord and plug adapter
- CanarE Straps (separate package) – not shown
- Clinic Cart (separate package) – not shown

Table 3 lists all the CanarE components and their model or catalogue numbers.

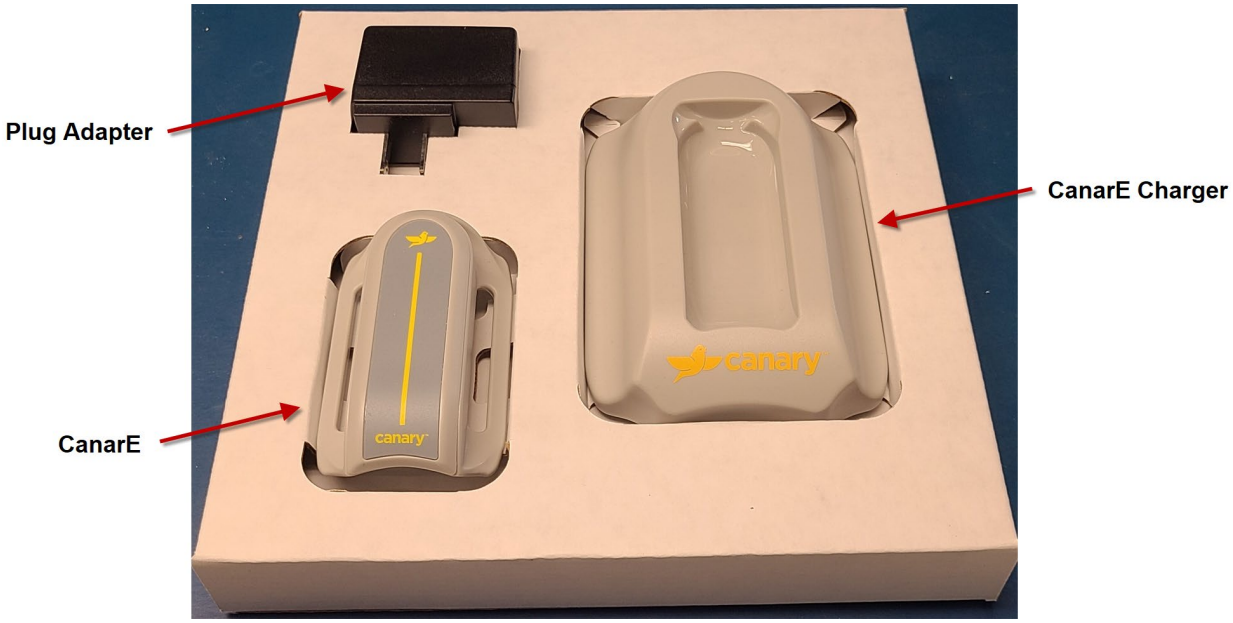


Figure 4: CanarE System Components Within Packaging

Table 3: CanarE System Components

Model or Catalogue Number	Description
43-5570-007-14	CanarE
43-5570-007-15	CanarE Charging Cradle
43-5570-007-16	CanarE Straps
43-5570-008-14	Clinic Cart

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.

7. Device Description

The CanarE System combines physical components, electronics, software, and user interfaces to collect, store, and transmit patient kinematic data for physician review. Table 3 lists the CanarE System components and interfaces. All physical components of the CanarE System, except the straps, are reusable and supplied non-sterile. The cleaning and disinfecting instructions for components can be found in Section 10.2. The CanarE straps are single-use, disposable that are provided non-sterile.

The HCP will attach the CanarE to the patient, then use the Clinic Base Station to perform data collection from the CanarE while the patient performs a selected test. After testing is complete, the Clinic Base Station retrieves the data collected from the CanarE to be processed and reviewed in the Clinic App.

The CanarE System allows preoperative patient evaluation to establish a patient's baseline data prior to receiving a CTE implant. Alternatively, the CanarE System may be used postoperatively on patients who receive a non-Canary implant where objective, functional mobility data is desired. Lastly, the CanarE may also be used postoperatively on patients with a CTE implant if desired.

7.1. The CanarE and Straps

The CanarE is a physical component that the HCP attaches to the patient's knee with the provided elastic, nylon, and Velcro Straps or with self-adhesive tape. The CanarE is an external wearable device intended to mimic a CTE implant, using similar software and electronics embedded within the device to collect the patient's functional movement and gait parameter information. The CanarE collects, stores, and transmits data when queried by the Clinic Base Station. The collected data from the CanarE is processed by the Clinic Base Station System for review.

The CanarE and Straps, intact skin contacting, material consists of polycarbonate and acrylonitrile / butadiene styrene (PC/ABS), Cycoloy, polyester, nylon, and Velcro.

7.2. The CanarE Charger

The CanarE Charger is a wireless charging device that recharges the CanarE internal battery. It is designed with a cavity to hold the CanarE while charging. The charger includes a power cord to connect to a power source.

The CanarE Charger, intact skin contacting, material consists of polycarbonate and acrylonitrile / butadiene styrene (PC/ABS), Cycoloy and polyvinyl chloride (PVC).

7.3. The Clinic Cart

The Clinic Cart is designed to store, provide a power source, and transport the components of the Clinic Base Station and CanarE Systems. Figure 5 shows an image of the Clinic Cart. It has a flat top surface for the Clinic Laptop and provides a working surface, a holder for the Clinic Base Station, and a drawer to store CanarE devices, a CanarE Charger, and CanarE Straps.

The Cart has power strips and power cables to provide power to the Clinic Laptop, Clinic Base Station, and CanarE Charger. The Clinic Cart also has wheel brakes to hold its position when needed and can transport all components around the clinic environment.

Figure 5: Clinic Cart

The Clinic Cart, intact skin contacting, material consists of high-density polyethylene (HDPE) and glass fiber reinforced nylon.

8. Directions for Use

The following information describes the use of the CanarE System in sequential order. This information is provided from an HCP's perspective. It is intended to provide directions for HCPs (including surgeons, surgeon's staff, physicians, and nurses) in using the CanarE System. It is also intended to inform HCPs about their patient's role in the use of the system to support patients' understanding of their health care needs.

8.1. Getting Started: CanarE

1. Remove all components from their packaging. See Figure 4.

   NOTE: Straps are provided separately.

2. Make sure that there are no damaged components. If damage is observed do not use.

3. Connect the CanarE Charger to power with the supplied power cord and plug adapter. A USB power supply may also be used without the plug adapter.

   NOTE: The Clinic Cart contains a power source for the CanarE Charger.

4. Place the CanarE flat surface down (logo face up) into the CanarE Charger holder as shown in Figure 6 and Figure 7. The CanarE contains an LED that will indicate its charge status while charging, as defined in Table 4.

   NOTE: See troubleshooting steps in Section 14 if the CanarE LED is a constant yellow.

5. When ready to use the CanarE, remove it from the Charger. The CanarE automatically powers on.

Figure 6: CanarE Charger

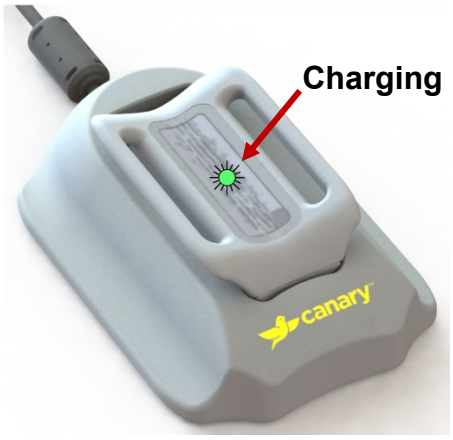


Figure 7: CanarE Charger with CanarE

Table 4: CanarE LED Charging Status

LED Status	Definition
Constant Green	Charging: CanarE battery status is between 85% -100% charged
Flashing Green	Charging: CanarE battery status is between 40-84% charged
Flashing Orange	Charging: CanarE battery status is between 20-39% charged
Constant Orange	Charging: CanarE battery status is between 0-19% charged

8.2. Attaching the CanarE to a Patient

1. With the patient sitting or standing, palpate the knee to locate the patient's left or right tibial tuberosity according to the Test Plan created with the Clinic Base Station System (Left Knee or Right Knee selected from the Clinic App Patient Test Plan).

   NOTE: The CanarE is an external wearable device intended to mimic a CTE implant by positioning it in the approximate location of a CTE implant as shown in Figure 8.

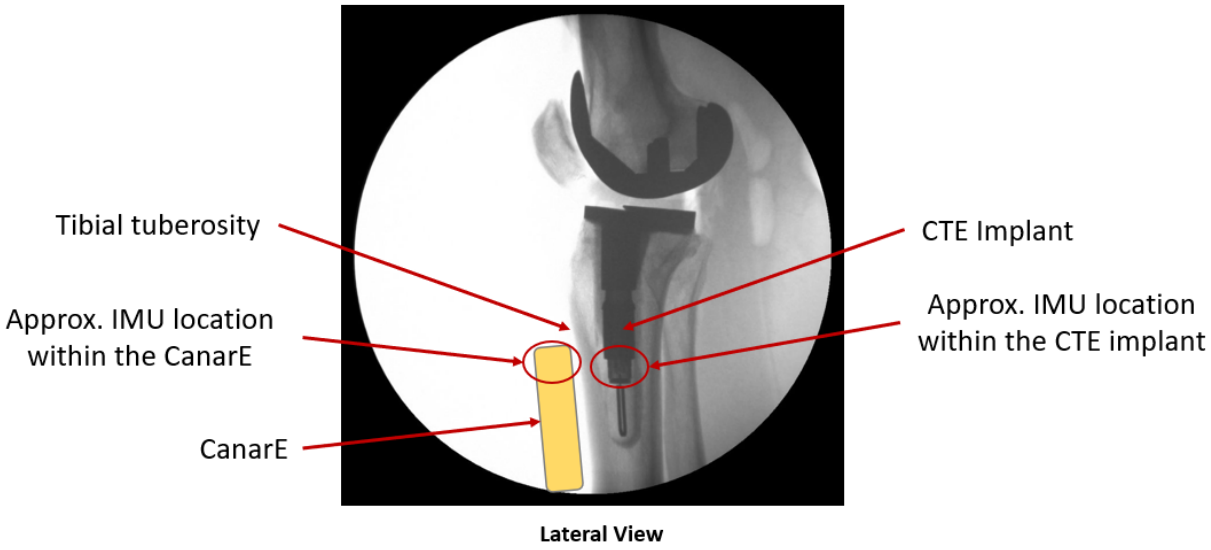


Figure 8: CanarE Placement Positioned in the Approximate Location of a CTE Implant

2. Place the CanarE directly onto the patient's knee with the superior surface of the CanarE located on the inferior most aspect of the tibial tuberosity as shown in Figure 9.

   NOTE: Do NOT place the CanarE over patient clothing. This may cause an unintended shift of the CanarE during testing, which will affect test result data.

3. Align the CanarE alignment mark with the axis of the tibia by palpating the patient's tibia inferior of the CanarE. Attach the CanarE as shown in Figure 9.

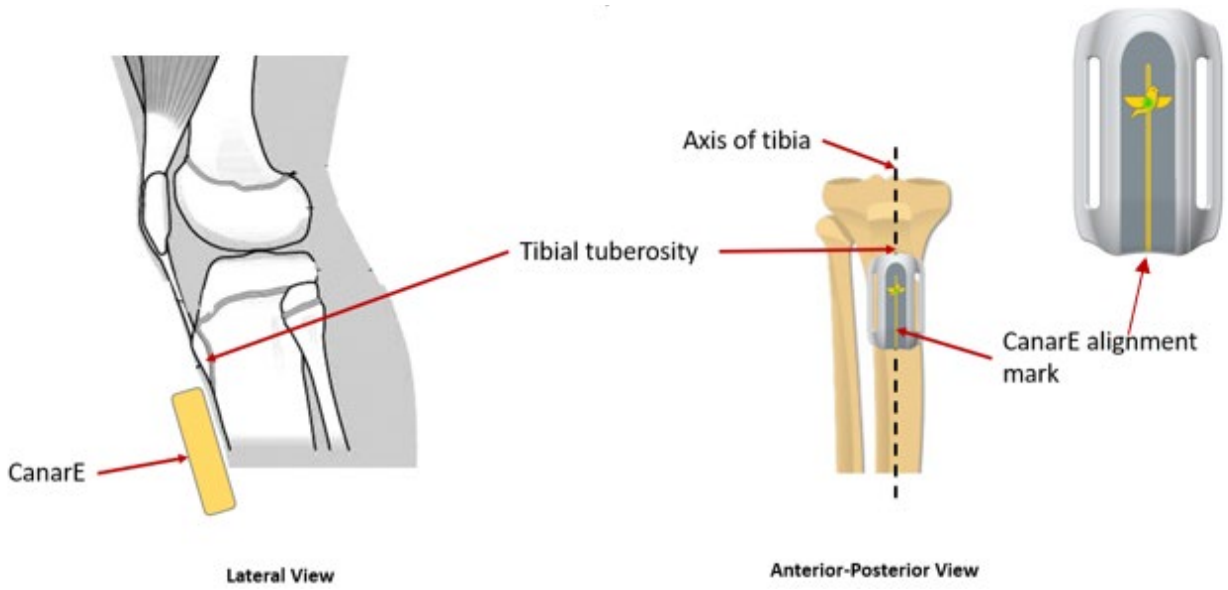


Figure 9: CanarE Placement on Tibia

4. Use the straps provided or self-adhesive tape to securely attach the CanarE to the patient.
    a. If using the CanarE Straps, follow the steps below as shown in Figure 10:
        i. Loop one end of the strap through the lateral slot of the CanarE and secure the Velcro to the strap.
        ii. Wrap the other end of the strap around the patient's leg then through the other lateral slot of the CanarE.
        iii. Pull the strap tight and use the Velcro to secure it.

    NOTE: When pulling the strap tight to secure the CanarE to the patient, the CanarE may slightly shift on the patient's leg. Make sure that placement of the CanarE on the patient's leg has not changed. If the CanarE has shifted, readjust its position to the correct location. If the position is not corrected, this may affect the CanarE data collection.

    NOTE: Make sure the CanarE and strap are not too tight by asking the patient.

        iv. Check placement and adjust if needed.

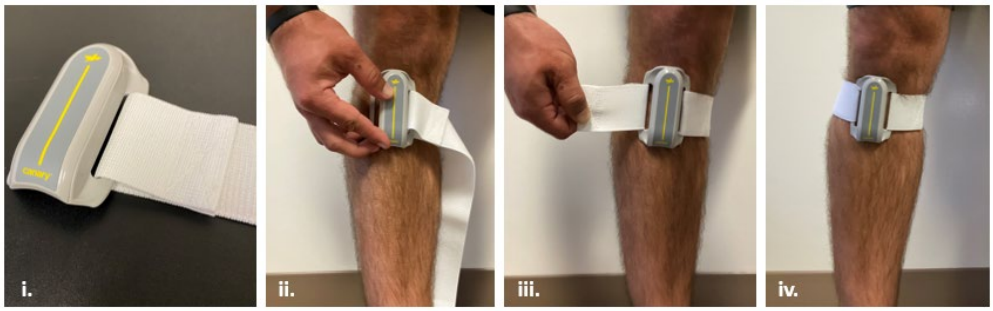


Figure 10: Attaching CanarE with Strap

b. If using the self-adhesive tape:

    i. Wrap the self-adhesive tape around the CanarE and patient's knee multiple times with overlap to secure the CanarE.

    NOTE: When pulling the self-adhesive tape tight to secure the CanarE to the patient, the CanarE may slightly shift on the patient's knee. Make sure the CanarE placement on the patient's knee has not changed. If the CanarE has shifted, readjust its position to the correct location. If the position is not corrected, this may affect the CanarE data collection.

5. Instruct the patient to walk with the CanarE attached to their knee. Observe and make sure the CanarE is secure and is not shifting position while the patient walks. Adjust the CanarE as needed.

    NOTE: Ask the patient if the CanarE feels uncomfortable or too loose and make adjustments.

8.3. Performing Data Collections with the CanarE

1. Enter the CanarE serial number, found on the patient's device label, into the Clinic App (see the Clinic Base Station System IFU).
2. Follow the Clinic Base Station System IFU to perform data collection using the CanarE.
3. During data collection, the CanarE LED will indicate when the CanarE is active. The LED status is defined in Table 5.

    NOTE: See troubleshooting steps in Section 14 if the CanarE LED is a constant yellow.

Table 5: CanarE LED Active Status

LED Status	Definition
Constant Green	Active: CanarE battery status is between 85% -100% charged
Flashing Green	Active: CanarE battery status is between 40-84% charged
Flashing Orange	Active: CanarE battery status is between 20-39% charged
Constant Orange	Active: CanarE battery status is between 0-19% charged

4. Remove the CanarE from the patient's knee when testing is complete.
5. Dispose of the Straps or self-adhesive tape.

   CAUTION Do not reuse the Straps; dispose after use.

8.4. Using the Clinic Cart

1. Assemble the Clinic Cart following the instructions provided in its packaging (K03-CRT-800000).
2. Connect the Cart's power cord to a standard outlet power supply.

   NOTE: The Cart's power supplies will not be active unless the Cart's power cord is connected to standard outlet power supply.
3. The Cart can transport components by releasing the wheel's brakes, and then pushing it to the desired location. Once in the desired location, set the brakes to keep the Cart from moving.

8.4.1. Clinic Laptop Placement and Power Supply

1. Place the Clinic Laptop in the desired location on the Clinic Cart's top flat service.
2. Connect the Clinic Laptop to the Laptop Power Supply as illustrated in Figure 11.

8.4.2. Clinic Base Station Placement and Power Supply

1. Place the Clinic Base Station in the holder on the Clinic Cart's top flat service as illustrated in Figure 11.
2. Connect the Clinic Base Station to the charging cord as illustrated in Figure 11.

   NOTE: The Clinic Base Station will be connected to the Clinic Laptop for use if both are connected to a power source on the Clinic Cart and powered on.

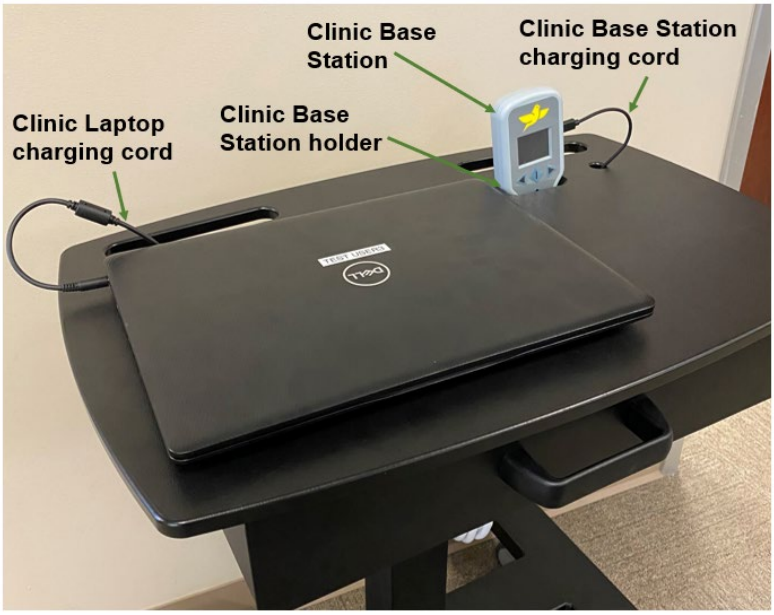


Figure 11: Clinic Cart with Clinic Base Station

8.4.3. CanarE Placement and Power Supply

1. The CanarE, CanarE Charger, and Straps can be stored in the Clinic Cart drawer as illustrated in Figure 12.

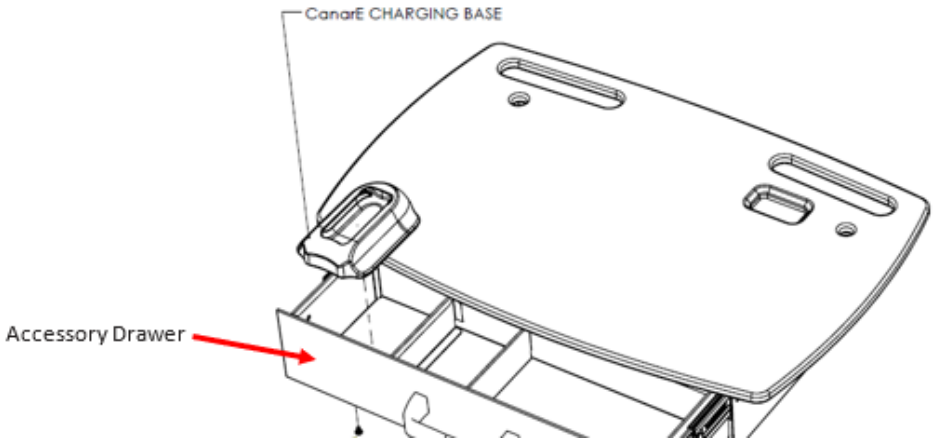


Figure 12: CanarE and CanarE Charger Placement

9. Data Security and Patient Privacy

All communication between the CanarE and the Clinic Base Station employs a unique communication protocol, with each CanarE having a unique Radio ID that is assigned to it in manufacturing. A Clinic Base Station can communicate with only one CanarE at a time using this Radio ID.

The communication between the Clinic Base Station and CanarE device is also encrypted with the unique encryption key assigned during the manufacture of the CanarE. In addition, communication integrity as well as data integrity checks are applied on the data received at both ends.

The Canary Medical Cloud Platform is designed for assuring HIPAA compliance. 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 Clinic Base Station decrypts messages and data from the CanarE, adds the serial number of the CanarE package, and then encrypts the unprocessed data before transmitting that data to the Cloud. The communication and data are checked for integrity by the Cloud application before it is processed.

Patients must consent to the CanarE data collection, storage, analysis, and sharing their CanarE and basic personal and health data with an HCP(s) they designate to provide their healthcare. As such, data will be identifiable to their healthcare provider and authorized administrators of the Canary Medical CanarE System. The patient will have the right to be forgotten and can turn off device data collection after a minimum required time for data generation. If the patient does not wish to consent, they can receive the standard of care.

Each HCP user is assigned a unique username and will be prompted to enter a password at initial login. The unique username and password are needed for logging into their account thereafter and for accessing the Clinic App.

10. Component Maintenance

10.1. Updating a CanarE

This section describes how to update the CanarE. The Clinic App and Clinic Base Station are required to update the CanarE.

1. Launch and log into the Clinic App as described in the Clinic Base Station System IFU.

   NOTE: Internet connection is required to download CanarE updates.

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

   NOTE: The Clinic Base Station must be connected to the Clinic Laptop and powered on to update the CanarE.

3. When selecting a CanarE device to create a patient Test Plan, as described in the Clinic Base Station System IFU, the Clinic App will check for available updates for the selected CanarE.

4. Make sure the selected CanarE device requiring an update is within six (6) feet of the Clinic Base Station.

   NOTE: Make sure there are no objects between the Clinic Base Station and the CanarE that may interfere with the connection.

5. Select the option to update the CanarE displayed in the Clinic App. The Clinic App will automatically download the update onto the Clinic Base Station.

   The Clinic Base Station will then connect to the CanarE and automatically update the device.

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

NOTE: The Clinic App will not allow you to use a CanarE that requires an update.

10.2. CanarE, CanarE Charger, and Clinic Cart Cleaning

Maintain the CanarE and accessories by keeping them clean, dry, and free of surrounding clutter.

The CanarE, CanarE Charger, and Clinic Cart 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 CanarE, CanarE Charger, and Clinic Cart.

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.

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 safely cleaning the CanarE, CanarE Charger, and Clinic Cart. Wipe the devices 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 CanarE, CanarE Charger, or accessories in water or cleaning agents as this could cause electrocution.

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

10.3. Clinic Cart Maintenance

Before first use and after periods of non-use, check the Clinic Cart for proper operation. If the Cart does not operate correctly, contact Canary Medical.

- Check the overall appearance of the Cart for any obvious damage or wear.
- Periodically inspect the casters and brakes. Remove all foreign material picked up by the casters and brakes.

11. Service Life

The CanarE and accessories are intended to last for 3 years and can be replaced if they become non-operational.

12. Servicing

If a CanarE or accessory is not working properly or even changes in performance, please see Section 14 for troubleshooting and potential solutions to the problem. If the issue cannot be fixed, please call Canary Medical for instructions on how to further troubleshoot the problem or return the unit for replacement.

13. Disposal

Contact your local authorities to determine the proper disposal method of CanarE units and accessories as electronics waste or return them to Canary Medical.

14. Troubleshooting

Table 6 lists steps that will generally solve issues encountered on the CanarE System. If the problem persists, contact Canary Medical Support.

Table 6: CanarE System Troubleshooting

Issue	Troubleshooting Steps
LED is not on while CanarE is charging	Make sure the CanarE Charger is connected to power. If using the Clinic Cart power source, make sure the Cart is connected to a power outlet. The LED has a timeout if it has been in the CanarE Charger too long. Remove the CanarE from the Charger and return it to the Charger to reset the device.
LED on the CanarE is yellow	Indicates a device fault. Place the CanarE in the CanarE Charger, remove, and then return to the CanarE Charger to reset the device.
Clinic Cart is not providing power	Make sure the Clinic Cart is connected to a power outlet. Make sure the power cords are properly connected to the Clinic Cart power supplies.

15. Component Specifications

Table 7: CanarE System Specifications

CanarE and Charger	Specification
Weight	**CanarE**: 50 g **CanarE Charger:** < 280 g
Dimensions	**CanarE**: 25.6 x 53.3 x 87.1 mm **CanarE Charger**: 30.9 x 91.8 x 128.0 mm
Power Source	**CanarE Charger External Supply**: 100-240V 50-60 Hz Class II **CanarE:** internally battery-powered
Mode of Operation	**Operational Modes:** • Normal operation • Fault (self-test failure) **Mode of Operation (Continuous):** The HCP uses the CanarE System before, during, and after on demand clinic data collection. It is used to perform on demand data collection, as well as transport and store components. The CanarE System consists of a CanarE, CanarE Charger, and Clinic Cart.
Recommended Operating Conditions	**Temperature:** 15°C to 30° C **Relative Humidity**: 10% to 90% (non-condensing) **Atmospheric Pressure**: 70 kPa – 106 kPa
Storage Conditions	**Storage**: 15° C to 30° 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 – 106 kPa
Protection from Ingress of Liquids and Particles	Per IEC-60529, CanarE rated as IP22.
Audible Output Levels	None. (Not applicable.)
	**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)

Clinic Cart	Specification
Safe Working Load	28.7 kg
Dimensions	777 x 643 x 524 mm
Power Source	120V 60 Hz Class I
Recommended Operating Conditions	**Temperature:** 15°C to 30° C **Relative Humidity**: 10% to 90% (non-condensing) **Atmospheric Pressure**: 70 kPa – 106 kPa
Storage Conditions	**Storage**: -18° C to 38° C **Relative Humidity**: 10% to 90% (non-condensing)
Transport Conditions (Packaging Tested to ISTA 2C Standard)	**Temperature:** -18°C to 38°C **Relative Humidity**: 10% to 95% (non-condensing) **Atmospheric Pressure**: 50 kPa – 106 kPa

16. Electrical Safety and Standard

16.1. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter is intended for use in an electromagnetic environment as specified in Table 8. The customer or the user of the transmitter should make sure 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(s) away from each other.

16.2. Electromagnetic Immunity Specifications

Table 8. 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)]	

1. This test applies only to output lines intended to connect directly to outdoor cables.
2. SIP/SOPS that have a maximum cable length less than (10 feet) long are excluded.
3. Testing may be performed at other modulation frequencies identified by the Risk Management Process.
4. Calibration for current injection clamps shall be performed in a 150.
5. 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. The exception is 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 illustrated in Figure 6 of the general standard, applied in a bent or straight position.

6. Capacitive coupling shall be used.
7. 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.
8. r.m.s., before modulation is applied.
9. 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.

16.3. Electromagnetic Emissions

The CTE implant and CanarE device are intended for use in the electromagnetic environment specified in Table 9. Make sure that the transmitter is used in such an environment.

Table 9: Electromagnetic Emissions

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

1. 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.
2. 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.
3. 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.

16.4. 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.

17. 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 CanarE (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.

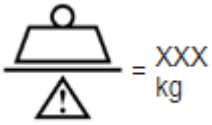
18. Patents and Trademarks

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.

19. Symbols Glossary

Symbol	Meaning	Designation Number and Title of 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
	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	

Symbol	Meaning	Designation Number and Title of Standard	Title of the Symbol in the Standard
	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 safety signs -- Registered safety signs	Refer to instruction manual/booklet
		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	ISO 15223-1 clause 5.3.5-6 Medical devices — Symbols to be used with medical device labels, labelling and	Temperature limit

Symbol	Meaning	Designation Number and Title of Standard	Title of the Symbol in the Standard
	See Table 12 for additional information.	information to be supplied	
	Transport and storage humidity limit ISO 7000-2620	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
	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	IEC 60601-1, (IEC 60529) clause 6.3; Table D.3	Degree of protection

Symbol	Meaning	Designation Number and Title of Standard	Title of the Symbol in the Standard
	degrees from vertical.		
	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 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

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