# QDOT MICRO™ Uni-Directional Navigation Catheter

## INSTRUCTIONS FOR USE

**Symbol Definitions**
Following definitions are for reference only. Please refer to the product label for applicable usage.

STERILE EO
Sterilized Using Ethylene Oxide


Do Not Re-Use


Caution


Consult Instructions for Use


Do not use if package is damaged.


Do not use if package is opened.


Keep Away from Sunlight


Keep Dry


Use-By Date

LOT
Batch Code

REF
Catalog Number


Contents: 1


Manufacturer


Date of Manufacture


Pin Connector

ELECTRODES EA
Electrodes

SPACING mm
Spacing


Temperature Limit

℞ only
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

x
Curve Type. Refer to label for colored circle containing applicable curve type.

NAV
Navigational Catheter

C3
Compatible with CARTO™ 3 EP Navigation System

# QDOT MICRO™ Uni-Directional Navigation Catheter

**Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.**

- STERILE. Sterilized using ethylene oxide.
- For single use only.
- Do not resterilize.
- Do not use if the package is open or damaged.

## DEVICE DESCRIPTION

The Biosense Webster QDOT MICRO™ Uni-Directional Catheter is a steerable multi-electrode luminal catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart and to transmit radiofrequency (RF) energy to the catheter tip electrode for ablation purposes. The catheter shaft measures 7.5 F with 8 F ring electrodes. For ablation, the catheter is used in conjunction with a compatible RF generator and a dispersive pad (indifferent electrode). The catheter has force-sensing technology that provides a real-time measurement of contact force between the catheter tip and the heart wall.

The catheter has a high-torque shaft with a uni-directional deflectable tip section containing an array of electrodes which includes a 3.5 mm tip dome. All of the electrodes may be used for recording and stimulation purposes. The tip electrode serves to deliver RF energy from the generator to the desired ablation site. The tip electrode and ring electrodes are made from noble metals. The catheter incorporates six thermocouple temperature sensors and three ECG electrodes that are embedded in the 3.5 mm tip electrode. A thumb knob is used to deflect the tip. The high-torque shaft also allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site. Three curve configurations designated “D,” “F,” and “J” are available.

At the proximal end of the catheter, a saline input port with a standard Luer fitting terminates from the open lumen. This saline port serves to permit the injection of normal saline to irrigate the tip electrode. During ablation, heparinized normal saline is passed through the internal lumen of the catheter and through the tip electrode, to irrigate and cool the ablation site as well as the electrode tip. A compatible irrigation pump is used to control the saline irrigation. The catheter interfaces with standard recording equipment and a compatible RF generator via accessory extension cables with the appropriate connectors.

This catheter features a location sensor embedded in the tip section that transmits location and contact force information to the CARTO™ 3 Navigation System. An appropriate reference device is required for location reference position purposes. For information on using the catheter in mapping procedures and for information on appropriate reference devices, refer to the user manual for the CARTO™ 3 Navigation System. For further description of the operation of the irrigation pump, the generator, and the CARTO™ 3 Navigation System, refer to the applicable instructions for use.

## INDICATIONS FOR USE

The Biosense Webster QDOT MICRO™ Uni-Directional Navigation Catheter and related accessory devices are indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a compatible radiofrequency generator, for the treatment of:

- Type I atrial flutter in patients age 18 or older.
- Drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with compatible three-dimensional electroanatomic mapping systems.

The Biosense Webster QDOT MICRO™ Uni-Directional Navigation Catheter provides a real-time measurement of contact force between the catheter tip and heart wall, as well as location information when used with CARTO™ 3 Navigation System.

## CONTRAINDICATIONS

Do not use this catheter:

1. If the patient has had a ventriculotomy or atriotomy within the preceding twelve weeks because the recent surgery may increase the risk of perforation.
2. In patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolus.
3. In patients with prosthetic valves as the catheter may damage the prosthesis.
4. In the coronary arterial vasculature due to risk of damage to the coronary arterial vasculature.
5. In patients with an active systemic infection because this may increase the risk of cardiac infection.
6. Via the transseptal approach in a patient with an interatrial baffle or patch because the opening could persist and produce an iatrogenic atrial shunt.
7. Via the retrograde trans-aortic approach in patients who have had aortic valve replacement.
8. With a long sheath or short introducer < 8.5 F in order to avoid damage to the catheter shaft.

## WARNINGS AND PRECAUTIONS

1. Do not use excessive force to advance or withdraw the catheter when resistance is encountered during catheter manipulation through the sheath.
2. Do not manually pre-shape the distal shaft of the catheter by applying external forces intended to bend or affect the intended shape or curve of the catheter.
3. Prior to use, the catheter must be warmed up as specified in the Directions for Use section of this document. If the catheter has not reached a steady state condition, there is potential for a zero-offset drift to occur which could result in an inaccurate contact force reading.
4. Always zero the contact force reading following insertion into the patient or when moving the catheter from one chamber of the heart to another. Ensure the catheter is not in contact with heart tissue prior to zeroing. Refer to the user manual for your CARTO™ 3 System for instructions on how to zero the contact force reading.
5. The contact force reading might become inaccurate if the contact force sensor (located between the first and second ring electrode) comes into close proximity with a ferrous material, such as the braided shaft of another catheter. If extreme fluctuations in force are observed, ensure the catheter's contact force sensor is not in close proximity with another catheter's shaft, check zero on the catheter and, if necessary, remove and inspect the catheter. The contact force reading is for information only and is not intended to replace standard handling precautions.
6. To ensure proper operation of the contact force sensor, the tip electrode and the two distal ring electrodes must protrude from the distal tip of the guiding sheath.
7. When applying high lateral force during mapping and RF application, the user should monitor the contact force dashboard and vector display on the CARTO™ 3 System screen to ensure that contact force measurements remain within the accurate range. Refer to the Error Messages and Alerts section of the CARTO™ 3 System user manual for system-related alert messages and indications related to inaccurate force readings.
8. Do not use the temperature sensor to monitor tissue temperature. The temperature sensor located within the tip section of the catheter does not reflect either electrode-tissue interface or tissue temperature due to the cooling effects of the saline irrigation of the electrode. The temperature displayed on the generator is the temperature of the hottest of the six thermocouples in the electrode, not tissue temperature. Monitoring the temperature from the electrode during the application of RF energy ensures that the irrigation flow rate is being maintained.
9. At higher contact force settings, rapid power increases during ablation may result in steam pops, which increase the risk of perforation.
10. This catheter may damage the mechanical or prosthetic valve of a patient if the catheter is accidentally advanced through the valve.
11. The safety of discontinuing anticoagulation therapy following catheter ablation of atrial fibrillation has not been established. Anticoagulation therapy in such patients should be administered in accordance with the AHA/ACC/HRS 2014 Guideline for the Management of Patients With Atrial Fibrillation.

12. The safety and effectiveness of radiofrequency ablation for the treatment of atrial fibrillation in patients with significant left ventricular dysfunction, advanced heart failure, substantial left atrial enlargement, and structural heart disease have not been established.
13. In accordance with your hospital's protocol, monitor the patient's fluid balance throughout the procedure to avoid fluid volume overload. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible. Prior to the procedure, always identify the patient's risk of volume overload.
14. Implantable pacemakers and implantable cardioverter/defibrillator (ICDs) may be adversely affected by RF energy. It is important to have temporary external sources of pacing and defibrillation available during ablation and to temporarily reprogram the pacing system to minimum output or OFF mode to minimize the risk of inappropriate pacing. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent leads; program the ICD to the OFF mode during the ablation procedure; and, perform complete implantable device analysis on all patients after ablation.
15. Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Patients who experience inadvertent complete AV block as a result of RF ablation may also require permanent pacing.
16. During the trans-aortic approach, adequate visualization is necessary to avoid placement of the catheter in the coronary vasculature. Intracoronary placement of the ablation catheter, RF energy application, or both have been associated with myocardial infarction.
17. To prevent stenosis of the pulmonary veins, do not place the catheter in the pulmonary veins during the application of RF energy.
18. When ablating near adjacent anatomical structures, take precautions to minimize collateral damage to the adjacent structures.
19. When ablating near the phrenic nerve, take precautions to avoid injuring the phrenic nerve, including appropriately reducing RF power, pacing to identify the proximity of ablation electrode(s) to the nerve and/or fluoroscopic evaluation of the diaphragm post ablation.
20. When ablating near the esophagus (along the posterior wall of the left atrium), take precautions to avoid injuring the esophagus. These may include beginning the ablation with reduced RF power, reducing contact force, reducing application time, increasing the time interval between ablations, moving to new location if temperature rise observed, esophageal visualization, and/or intraluminal esophageal temperature monitoring.
21. Minimize or eliminate X-ray exposure during the procedure. Catheter ablation procedures using fluoroscopic imaging may present the potential for significant X-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the X-ray beam intensity and duration of fluoroscopic imaging. Catheter ablation, when using fluoroscopic imaging, should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must therefore be given for the use of the device in pregnant women.
22. Do not expose the catheter to organic solvents such as alcohol.
23. Do not autoclave the catheter.
24. Do not immerse the proximal handle or cable connector in fluids. Electrical performance could be affected.
25. Do not scrub or twist the distal tip electrode during cleaning.
26. Inspect the saline within the irrigation tubing for air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause emboli.
27. Purge the catheter and irrigation tubing with heparinized normal saline prior to insertion of the catheter inside the patient body.
28. Electrophysiology catheters and systems are intended for use only in X-ray shielded rooms due to electromagnetic compatibility requirements and other hospital safety guidelines.
29. Do not attempt to operate the QDOT MICRO™ Uni-Directional Catheter or the generator prior to completely reading and understanding the applicable instructions for use.

30. Cardiac ablation procedures should be performed by appropriately trained personnel in a fully equipped electrophysiology laboratory. Appropriate clinical instruction in the use of the QDOT MICRO™ Uni-Directional Catheter should also be completed.
31. The long-term risks of protracted fluoroscopy and creation of RF induced lesions have not been established. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
32. To prevent thromboembolism, intravenous heparin (target ACT of $\geq$ 350 s) should be administered prior to or immediately following transseptal puncture during AF ablation procedures. The 2017 HRS/EHRA/ECAS/AOHRS/SOLAECCE expert consensus statement on catheter and surgical ablation of atrial fibrillation recommends systemic anticoagulation with warfarin or a direct thrombin or factor Xa inhibitor for at least 2 months following an AF ablation procedure (Calkins H, Hindricks G, Cappato R et al. 2017 HRS/EHRA/ECAS/AOHRS/SOLAECCE Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation. J Interv Card Electrophysiol. 2017 50:1-55).
33. When using the QDOT MICRO™ Uni-Directional Catheter with conventional systems (such as fluoroscopy or ultrasound imaging), or with the CARTO™ 3 Navigation System, careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under direct imaging guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. The firmness of the braided tip dictates that care must be taken to prevent perforation of the heart. The contact force reading is for information only and is not intended to replace standard handling precautions.
34. Always use the thumb knob to straighten the catheter tip before insertion or withdrawal of the catheter.
35. Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter.
36. When RF energy is interrupted for either a temperature or an impedance rise (the set limit is exceeded), the catheter should be removed, and the tip should be inspected for char/coagulum that may be present on the tip. If present, do not continue the procedure with the same catheter and replace the catheter. If no char/coagulum is present, flush the tip to ensure the irrigation holes are not plugged prior to reinsertion of the catheter inside the patient body.
37. Apparent low power output, high impedance reading, or failure of the equipment to function correctly at normal settings may indicate faulty application of the indifferent electrode(s) or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication of the indifferent electrode or other electrical leads.
38. Read and follow the indifferent electrode manufacturer's instructions for use. The use of indifferent electrodes that meet or exceed ANSI/AAMI requirements (AAMI IEC 60601-2-2), is recommended.
39. The QDOT MICRO™ Uni-Directional Catheter is intended for use with a compatible RF generator, compatible irrigation pump, CARTO™ 3 Navigation System, Biosense Webster cables, and other appropriate interface cables and connectors. Use of a compatible irrigation pump is recommended to assure proper irrigation flow rate.
40. Care should be taken when ablating near structures such as the sino-atrial and atrioventricular nodes.
41. The sterile packaging and catheter should be inspected prior to use. Do not use if the packaging or catheter appears damaged.
42. The catheter is sterilized with ethylene oxide gas and should be used by the "Use By" date on the device package. Do not use the catheter if it is past the "Use By" date.
43. The QDOT MICRO™ Uni-Directional Catheter is intended for single patient use only.
44. Do not resterilize and reuse.
45. Do not use near MRI equipment since movement or heating of the catheter may occur and the image on the display may become distorted.
46. Use both direct imaging guidance (such as fluoroscopy or ultrasound) and electrogram data to monitor catheter advancement and reduce risk of tissue injury.
47. The QDOT MICRO™ Uni-Directional Catheter used in conjunction with a compatible RF generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and indifferent electrode, particularly when operating the catheter. During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces.

48. The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical suite.
49. Electromagnetic interference (EMI) produced by the QDOT MICRO™ Uni-Directional Catheter, when used in conjunction with a compatible RF generator during normal operation, may adversely affect the performance of other equipment.
50. Electrodes and probes used for monitoring and stimulating devices can provide paths for high frequency current. The risk of burns can be reduced but not eliminated by placing the electrodes and probes as far away as possible from the ablation site and the indifferent electrode. Protective impedance may reduce the risk of burns, and permit continuous monitoring of the electrocardiogram during energy delivery.
51. If the generator does not display temperature, verify that the cables from the catheter to the CARTO™ System Patient Interface Unit (PIU) and the cable from the CARTO™ System Patient Interface Unit (PIU) to the generator are properly connected. If temperature still is not displayed, there may be a malfunction in the temperature sensing system that must be corrected prior to applying RF power.
52. The temperature measurement accuracy of the QDOT MICRO™ Uni-Directional Catheter, as with any temperature measurement electrophysiology catheter, is determined by the temperature accuracy of all of the connected devices. Please consult the appropriate user manuals for the connected devices for the temperature accuracy specification.
53. Before use, verify irrigation ports are patent by infusing heparinized normal saline through the catheter and tubing.
54. Regularly inspect and test reusable cables and accessories.

## ADVERSE EVENTS

**NOTE: The adverse events in the following summary were observed in clinical studies involving only the use of the QDOT Micro™ Catheter.**

**Clinical trial for the QDOT Micro™ Catheter – Pivotal Study (Q-FFICIENCY)**
Of the 177 subjects in the Safety Analysis Set, 7 primary adverse events (AEs) were reported in 6 subjects. See the “Summary of Clinical Studies Conducted for the QDOT Micro™ Catheter” section below for a complete description of the AEs encountered during the study.

## SUMMARY OF CLINICAL STUDIES CONDUCTED FOR THE QDOT MICRO™ CATHETER

The following is a summary of the pivotal study (Q-FFICIENCY) performed under IDE for the QDOT Micro™ Catheter, using model numbers D-1394-XX-SI and D-1395-XX-SI. Data from this clinical study formed the basis for the US FDA PMA approval decision.

All patients underwent informed consent per the study protocol, and in compliance with the Code of Federal Regulations, 21 §50. The protocol and informed consent materials were reviewed and approved by the appropriate IRB prior to subject enrollment, and in compliance with the Code of Federal Regulations, 21 §56. Per the requirements of 21 CFR §812.20(b)(5), all participating investigators signed the Clinical Study Agreement prior to enrollment at their center, which included financial disclosure forms, current curricula vitae for the investigator and co-investigators, and written IRB approval for the investigational study. The clinical study was monitored in a manner consistent with 21CFR, Part 812, Subpart C, *Responsibilities of Sponsor.* Monitoring visits included, but were not limited to, verification of all study logs, verification that informed consent was being obtained in accordance with requirements described in the study protocol for all subjects participating in the study, verification of completeness of the Regulatory Binder, data source verification with the eCRFs, and identification and action to resolve any issues or problems with the study.

**A. Objective**
The primary objective of this trial was to demonstrate the safety and effectiveness of the QDOT MICRO™ catheter when used with the nMARQ™ RF generator in the treatment of drug refractory symptomatic paroxysmal atrial fibrillation (PAF) during standard electrophysiology mapping and RF ablation procedures.

**B. Study Design**

The study was a prospective, single arm, unblinded, multicenter, pivotal clinical investigation conducted at 25 investigational sites in the US.

The study planned to enroll up to 185 subjects who are candidates for catheter ablation. Bayesian adaptive design was used to assess early success at one interim analysis performed 6 months after enrollment was completed and when 30% of subjects in the study completed 12 months of follow-up.

A CT/MRA imaging sub-study was integrated in the pivotal study. The first 40 consecutively enrolled subjects were included in the sub-study and underwent a 3-month CT/MRA in addition to the baseline CT/MRA to assess incidence of PV stenosis.

B.1 - Study Objectives and Endpoints:

The objectives and endpoints for this study are presented in Table 1. Failure modes for the primary effectiveness endpoint are listed in Table 2.

**Table 1 – Objectives and Endpoints for Q-FFICIENCY Study**

| Objectives | Endpoints |
|---|---|
| **Primary** | |
| To demonstrate the safety and 12-month effectiveness of the QDOT MICRO™ catheter when used with the nMARQ™ RF generator for pulmonary vein isolation (PVI) in the treatment of subjects with drug refractory symptomatic paroxysmal atrial fibrillation (PAF). | • Primary safety endpoint: Incidence of any primary adverse event occurring within 7 days of the AF ablation procedure (initial or repeat procedure) using the QDOT MICRO™ catheter, except atrio-esophageal fistula and PV stenosis, which may also be considered as primary adverse events if occurring greater than 7 days and up to 90 days post the ablation procedure. Primary adverse events included the following: Death, myocardial infarction, PV stenosis, phrenic nerve injury/diaphragmatic paralysis, atrio-esophageal fistula, TIA, stroke/CVA, thromboembolism, pericarditis, cardiac tamponade/perforation, vagal nerve injury, major vascular access complications/bleeding, pulmonary edema (respiratory insufficiency), and heart block.<br>• Primary effectiveness endpoint: Freedom from documented atrial fibrillation (AF), atrial tachycardia (AT) or atrial flutter (AFL) (hereinafter collectively referred to as “atrial tachyarrhythmias") recurrence during the evaluation period (Day 91 through Day 365) and freedom from the following failure modes (defined in Table 2):<br>o Acute procedure failure<br>o Repeat ablation failure<br>o Antiarrhythmic drug failure |

| Objectives | Endpoints |
|---|---|
| **Secondary** | |
| To evaluate the incidence of (serious) adverse events during and after procedure up to 3 months following procedure | • Incidence of Unanticipated Adverse Device Effects (UADEs)<br>• Incidence of Serious Adverse Events (SAEs) within 7 days (early onset), > 7 to 30 days (peri-procedural) and > 30 days (late onset) of initial ablation<br>• Incidence of bleeding complication (ISTH definitions): a) major, b) clinically relevant non-major and c) minor bleeding |
| To evaluate Acute Procedural Success defined as confirmation of entrance block in all PVs | • Acute procedural success: Percent of subjects with electrical isolation of PVs (entrance block) at the end of the procedure<br>o The percent of subjects with electrical isolation of PVs (entrance block) using QMODE+ as only ablation strategy<br>• Percent of subjects with electrical isolation of PVs (entrance block) after first encirclement (evaluated prior to the 20-minute waiting period and adenosine/isoproterenol challenge)<br>• Percent of subjects with electrical isolation of all PVs (entrance block) after first encirclement without acute reconnection, after waiting period and adenosine/isoproterenol challenge<br>• Percent of subjects and % of PVs with touch-up (i.e. touch-up is used to remove ablation of acute reconnection) among all targeted veins and touch-up location<br>• Anatomical location of acute PV reconnection after first encirclement |
| To evaluate repeat ablation procedures during the 12-month period post-procedure | • Incidence (%) of repeat ablation procedures<br>• Percent PVs re-isolated among all the targeted PVs at repeat procedure<br>• Percent repeat ablation procedures requiring new linear lesions and/or identifying new foci outside of initially isolated area among the repeat ablation procedures |
| To evaluate the 12-month Single Procedure Success | • 12-month single procedure success: Freedom from documented AF/AFL/AT recurrence (episodes ≥ 30 secs) during the Effectiveness Evaluation Period after a single ablation procedure and off anti-arrhythmia drugs (AADs) during the effectiveness evaluation period |

**Table 2 – Failure Modes for Primary Effectiveness Endpoint**

| Failure Mode | Criteria |
|---|---|
| Acute procedural | • Failure to confirm entrance block in all pulmonary veins post-procedure.<br>• Use of a non-study catheter to treat left atrial ablation targets and cavo-tricuspid isthmus. |
| Repeat ablation | • > 2 repeat ablation procedures with the study catheter during the 3-Month blanking period (Day 0-90) after the index ablation procedure.<br>• Use of a non-study catheter to treat study arrhythmia ablation targets during the blanking period.<br>• Any repeat ablation procedure during the Evaluation Period. |
| Antiarrhythmic drug | • Taking a new Class I or III AAD for AF or a previously failed Class I or III AAD at a greater than the highest ineffective historical dose for AF during the evaluation period. |

B.2 - Safety and Effectiveness Performance Goals

B.2.1 - Safety Performance Goal

The study was designed to compare the primary safety endpoint to a pre-determined safety performance goal of 14%. Data from recent PAF ablation studies for devices similar to the device in the current study were reviewed as a first step to deriving the performance goal for the primary safety endpoint. A meta-analysis approach was taken to estimate the average composite endpoint rate. Based on the meta-analysis, the upper bound of the 95% confidence interval was estimated to be equal to 9%. The pre-determined performance goal of 14% would reflect an approximately 50% increase in risk from the upper bound of the 95% CI.

B.2.2 - Effectiveness Performance Goal

The study was designed to compare the primary effectiveness endpoint to a pre-determined performance goal of 50%, which is indicated as the minimum acceptable success rate at 12 months for a paroxysmal AF population in the 2017 HRS/EHRA/ECAS/APHRS/ SOLAECE Expert Consensus Statement on Catheter and Surgical Ablation of AF (Calkins, et al., 2017).

B.3 - Subject Accountability:

**Table 3 – Subject Accountability and Disposition**

| Subject Enrollment | n |
|---|---|
| Enrolled Subjects | 191 |
| Excluded Subjects | 14 |
| Study Catheter Inserted | 177 |
| Discontinued Subjects | 2 |
| RF Energy Delivered with Study Catheter | 175 |
| Death | 1 |
| Withdrawn | 7 |
| Early Termination Subjects | 0 |
| Lost to Follow Up Subjects | 5 |
| Completed Subjects | 162 |

Among the 191 enrolled subjects, 14 had no insertion of the study device and were excluded from the analysis sets for the following reasons:

- System connectivity related device deficiencies (n = 4)

- Not meeting study entrance criteria (n = 9)
- Occurrence of an adverse event (tamponade) before insertion of the study device (n = 1)

Two (2) subjects had the study catheter inserted but no RF applications were delivered due to system connectivity issues.

A total of 175 subjects received RF ablation using the study device. Among those, seven (7) subjects (4.0%) withdrew their consent and discontinued their study participation during follow-up from 48 to 384 days post ablation; five (5) subjects (2.9%) were lost to follow up between 104 days and 266 days post procedure; one (1) subject (0.6%) expired 7 months post procedure; and 162 subjects (92.6%) completed the 12-month follow-up visit.

B.3.1 - Subject Disposition

The following definitions were used to classify subjects:

**Table 4 – Subject Classifications**

| Disposition | Definition |
|---|---|
| Enrolled Subjects | Subjects who signed the informed consent. |
| Excluded Subjects | Subjects who were enrolled but never underwent insertion of the study catheter. |
| Discontinued Subjects | Subjects who had the investigational catheter inserted but did not undergo ablation (i.e., no RF energy was delivered via the study device). These discontinued subjects were followed up for 3 months. |
| Lost to Follow-up Subjects | Subjects who were enrolled, but contact was lost after the most recent follow-up visits (despite 3 documented attempts to contact the subject). |
| Withdrawn / Early Termination Subjects | Subjects who withdrew consent for study participation or were withdrawn by the investigator or were terminated from the study prior to completion of all follow-up visits. |
| Completed Subjects | Enrolled subjects who completed the 12-month follow-up visit and were not excluded, discontinued, withdrawn, early terminated, expired, or lost to follow-up from the study before the final study visit. |

B.3.2 - Analysis Sets

**Safety Analysis Set:** The Safety analysis set included all enrolled subjects who had the investigational device inserted, regardless of RF energy delivery.

**Modified Intent-To-Treat (mITT) Analysis Set:** The mITT analysis set consisted of all enrolled subjects who met all eligibility criteria and had the investigational device inserted.

**Per-Protocol (PP) Analysis Set:** The PP analysis set included subjects who satisfied the following criteria:

- Enrolled and met eligibility criteria
- Had undergone RF ablation
- Were treated with the study catheters and had been treated for the study related arrhythmia without major protocol deviations deemed to affect the scientific integrity of the study, included in the following list. No additional major protocol deviations beyond those below were identified that required exclusion of subjects from the Per Protocol analysis set
    - Missing all protocol-specified electronic effectiveness monitoring
    - Esophageal monitoring was not done per protocol and risk was not mitigated
    - The required waiting period of 20 minutes was not followed before pacing procedures and/or infusion of cardiac medications to induce AF/reconnection was not performed before the entrance block confirmation.

**Treatment Received Analysis Set:** The Treatment Received analysis set included all enrolled subjects who received RF ablation using the study catheter. This analysis set was created post-hoc because it was deemed relevant by the FDA.

**CT/MRA Analysis Set:** The CT/MRA set consisted of the first 40 subjects who are consecutively enrolled in the main arm of the study with 3-month CT/MRA assessment. The subject must have readable outcomes at baseline and 3 months.

## C. Results

C.1 - Subject Demographics:

**Table 5 – Subject Demographics (Enrolled Subjects, N=191)**

| Variables | All Subjects (N=191) | Safety Analysis Set (N=177) | mITT Analysis Set (N=167) | Per-Protocol Analysis Set (N=166) |
|---|---|---|---|---|
| Age (years) [1] | | | | |
| n | 191 | 177 | 167 | 166 |
| Mean | 63.5 | 63.3 | 63.1 | 63.2 |
| SD | 10.69 | 10.88 | 11.00 | 11.03 |
| Min/Max | 24 / 83 | 24 / 83 | 24 / 83 | 24 / 83 |
| Sex, n/N (%) | | | | |
| Male | 116 / 191 (60.7) | 106 / 177 (59.9) | 101 / 167 (60.5) | 101 / 166 (60.8) |
| Female | 75 / 191 (39.3) | 71 / 177 (40.1) | 66 / 167 (39.5) | 65 / 166 (39.2) |
| Race n (%) | | | | |
| White, n/N (%) | 166 / 191 (86.9) | 157 / 177 (88.7) | 149 / 167 (89.2) | 148 / 166 (89.2) |
| Black or African American | 7 / 191 (3.7) | 6 / 177 (3.4) | 6 / 167 (3.6) | 6 / 166 (3.6) |
| Asian | 1 / 191 (0.5) | 1 / 177 (0.6) | 1 / 167 (0.6) | 1 / 166 (0.6) |
| Race not reported | 17 / 191 (8.9) | 13 / 177 (7.3) | 11 / 167 (6.6) | 11 / 166 (6.6) |
| Ethnicity, n/N (%) | | | | |
| Not Hispanic or Latino | 164 / 191 (85.9) | 154 / 177 (87.0) | 146 / 167 (87.4) | 145 / 166 (87.3) |
| Hispanic or Latino | 8 / 191 (4.2) | 6 / 177 (3.4) | 6 / 167 (3.6) | 6 / 166 (3.6) |
| Not reported | 19 / 191 (9.9) | 17 / 177 (9.6) | 15 / 167 (9.0) | 15 / 166 (9.0) |

C.2 - Baseline Characteristics:

**Table 6 – Medical History (Enrolled Subjects, N=191)**

| Medical History | Enrolled Subjects (N=191) | Safety Analysis Set (N=177) | mITT Analysis Set (N=167) | Per-Protocol Analysis Set (N=166) |
|---|---|---|---|---|
| **Cardiovascular** | 156 / 191 (81.7) | 143 / 177 (80.8) | 135 / 167 (80.8) | 134 / 166 (80.7) |
| Congestive heart failure | 16 / 191 (8.4) | 10 / 177 (5.6) | 9 / 167 (5.4) | 9 / 166 (5.4) |

| Medical History | Enrolled Subjects (N=191) | Safety Analysis Set (N=177) | mITT Analysis Set (N=167) | Per-Protocol Analysis Set (N=166) |
|---|---|---|---|---|
| Coronary artery disease | 39 / 191 (20.4) | 36 / 177 (20.3) | 33 / 167 (19.8) | 33 / 166 (19.9) |
| Vascular disease | 25 / 191 (13.1) | 23 / 177 (13.0) | 22 / 167 (13.2) | 22 / 166 (13.3) |
| Myocardial infarction | 13 / 191 (6.8) | 12 / 177 (6.8) | 10 / 167 (6.0) | 10 / 166 (6.0) |
| Hypertension | 131 / 191 (68.6) | 122 / 177 (68.9) | 116 / 167 (69.5) | 115 / 166 (69.3) |
| Cardiomyopathy | 15 / 191 (7.9) | 11 / 177 (6.2) | 10 / 167 (6.0) | 10 / 166 (6.0) |
| Left ventricular hypertrophy | 1 / 191 (0.5) | 1 / 177 (0.6) | 1 / 167 (0.6) | 1 / 166 (0.6) |
| Significant valvular disease | 3 / 191 (1.6) | 1 / 177 (0.6) | 1 / 167 (0.6) | 1 / 166 (0.6) |
| **Thromboembolic Events** | 20 / 191 (10.5) | 18 / 177 (10.2) | 16 / 167 (9.6) | 16 / 166 (9.6) |
| Transient ischemic attack | 5 / 191 (2.6) | 4 / 177 (2.3) | 3 / 167 (1.8) | 3 / 166 (1.8) |
| Stroke | 6 / 191 (3.1) | 5 / 177 (2.8) | 5 / 167 (3.0) | 5 / 166 (3.0) |
| Pulmonary embolus | 2 / 191 (1.0) | 2 / 177 (1.1) | 2 / 167 (1.2) | 2 / 166 (1.2) |
| **Diabetes** | 37 / 191 (19.4) | 36 / 177 (20.3) | 33 / 167 (19.8) | 33 / 166 (19.9) |
| **Obstructive Sleep Apnea** | 50 / 191 (26.2) | 46 / 177 (26.0) | 44 / 167 (26.3) | 44 / 166 (26.5) |
| CPAP Use | 36 / 191 (18.8) | 34 / 177 (19.2) | 33 / 167 (19.8) | 33 / 166 (19.9) |
| **$CHA_2DS_2$-VASc score** | 2.4 ± 1.51 | 2.4 ± 1.53 | 2.4 ± 1.49 | 2.4 ± 1.50 |
| **AF History (months)** | 48.6 ± 73.63 | 49.6 ± 75.29 | 51.7 ± 76.92 | 51.9 ± 77.11 |
| **PAF Episodes Within 12 Months** | 24.9 ± 89.91 | 25.2 ± 92.80 | 26.0 ± 95.22 | 25.7 ± 95.38 |
| **AAD Failed- Class I&III** | 1.2 ± 0.50 | 1.2 ± 0.50 | 1.2 ± 0.52 | 1.2 ± 0.52 |
| **Arrhythmia other than Atrial Fibrillation** | 87 / 191 (45.5) | 81 / 177 (45.8) | 73 / 167 (43.7) | 73 / 166 (44.0) |
| Left/right Atrial Tachycardia (AT) | 8 / 191 (4.2) | 8 / 177 (4.5) | 7 / 167 (4.2) | 7 / 166 (4.2) |
| Supraventricular Tachycardia (SVT) | 22 / 191 (11.5) | 20 / 177 (11.3) | 14 / 167 (8.4) | 14 / 166 (8.4) |
| Atrial flutter (AFL) | 43 / 191 (22.5) | 41 / 177 (23.2) | 40 / 167 (24.0) | 40 / 166 (24.1) |
| AVNRT | 0 / 191 (0.0) | 0 / 177 (0.0) | 0 / 167 (0.0) | 0 / 166 (0.0) |
| Accessory pathway | 0 / 191 (0.0) | 0 / 177 (0.0) | 0 / 167 (0.0) | 0 / 166 (0.0) |
| Ventricular tachycardia | 2 / 191 (1.0) | 2 / 177 (1.1) | 2 / 167 (1.2) | 2 / 166 (1.2) |
| **LA Diameter (mm)** | 38.06 ± 6.042 | 37.95 ± 5.917 | 38.09 ± 5.974 | 38.16 ± 5.917 |
| **LVEF (%)** | 59.4 ± 7.31 | 59.6 ± 7.02 | 59.7 ± 6.98 | 59.7 ± 6.99 |

Values in table represent n/N (%) or mean ± SD, as appropriate.

C.3 - Index Ablation Procedure

**Ablation protocol**

A circumferential anatomical approach was used to isolate all PVs. Confirmation of entrance block in all PVs was required by the protocol with a 20-minute waiting period after the last PV encircling lesion, during isoproterenol infusion and/or after adenosine bolus.

The study ablation procedure used both QMODE and QMODE+ temperature control modes. The primary mode of ablation for PVI was QMODE+. QMODE was used for PVI once the investigator deemed

QMODE+ unable to complete PVI. QMODE was used primarily for RF application outside the PV ostia and for touch-up of the PVI, if necessary.

Table 7 and Table 8 present the ablation parameters for the QMODE+ mode and QMODE mode, respectively.

**Table 7 – QMODE+ RF and Flow Rate Settings during RF applications**

| Power (W) | Target Temp (ºC) | | Cut-off Temp (ºC) | | Nominal Irrigation Flow rate (mL) |
|---|---|---|---|---|---|
| | Range | Maximum allowed | Range | Maximum allowed | |
| 90† | 40-60 | 60 | 60-70 | 70 | 8 |

† RF applications at this setting were limited to 4 sec. It was recommended to use lower target temperature setting for the posterior wall RF applications.

**Table 8 – QMODE Ablation Parameters***

| Power (W) | Target Temp (ºC) | | Cut-off Temp (ºC) | | Nominal Irrigation Flow rate (mL) |
|---|---|---|---|---|---|
| | Range | Recommended | Range | Recommended | |
| 25-35 | 45-50 | 50 | 50-55 | 55 | 4 |
| 36-50 | 45-50 | 50 | 50-55 | 55 | 15 |

* The study protocol recommended a maximum duration of 60 sec for RF applications using QMODE in general. For RF applications on the left atrial posterior wall, a maximum power of 35 W and a maximum duration of 30 sec were recommended.

Linear ablation lines were only required to treat documented macro-re-entry atrial tachycardias (ATs) and limited to the following targets only:

- LA roof line;
- Mitral Valve (MV) isthmus line;
- LA floor line;
- Cavo tricuspid isthmus (CTI).

A right atrial CTI linear ablation was required in cases with documented typical atrial flutter either before or during the procedure.

Prophylactic ablation of empirical sites was not allowed.

Ablation of spontaneous non-PV triggers was required.

Complex fractionated atrial electrogram (CFAE) ablation was not recommended.

All linear lesions required confirmation of bidirectional conduction block by pacing and/or mapping maneuvers.

The recommended contact force working range was 5-30 grams for both QMODE and QMODE+ modes.

**Procedural Data**

Among the 166 subjects in the PP analysis set, 59 subjects underwent the entire index procedure using QMODE+ mode only and 107 subjects using both QMODE+ & QMODE modes. QMODE+ only was used for PVI in 91 subjects in the PP cohort. Of the 91 subjects, 32 subjects received ablations outside PVs as well using QMODE.

Table 9-11 present the procedural data of the index procedures.

**Table 9 – Summary of Power, Temperature and Impedance Data Per Procedure (Per-Protocol Analysis Set, N=166)**

| Description | QMODE+ Only n=59 | QMODE+ and QMODE n=107 |
|---|---|---|
| Average Power (W) | 84.333 ± 0.4099 | 75.893 ± 7.5338 |
| Average Temperature (°C) | 39.415 ± 2.5587 | 39.555 ± 2.6122 |
| Average Impedance Drop (ohms) | 9.59 ± 1.696 | 9.47 ± 2.434 |

Values in table represent mean ± SD.

**Table 10 – Summary of Ablation Procedure Parameters (Per-Protocol Analysis Set, N=166)**

| Variable | Per- Protocol Analysis Set, N=166 | QMODE+ Only, N=59 | QMODE + and QMODE Combined N=107 |
|---|---|---|---|
| **Total mapping time (min)** | | | |
| n | 166 | 59 | 107 |
| Mean ± SD | 10.49 ± 10.593 | 10.29 ± 7.575 | 10.61 ± 11.968 |
| **Total procedure time (min)** | | | |
| n | 166 | 59 | 107 |
| Mean ± SD | 144.26 ± 51.101 | 122.27 ± 28.463 | 156.38 ± 56.604 |
| **Total fluoroscopy duration (min)** | | | |
| n | 165 | 59 | 106 |
| Mean ± SD | 10.81 ± 10.600 | 8.65 ± 7.935 | 12.01 ± 11.690 |
| **Total time to achieve PVI (min)** | | | |
| n | 165 | 58 | 107 |
| Mean ± SD | 25.32 ± 33.948 | 16.38 ± 20.891 | 30.17 ± 38.483 |
| **Total RF application time for ablating PVs (min)** | | | |
| n | 165 | 58 | 107 |
| Mean ± SD | 11.66 ± 11.322 | 7.33 ± 5.273 | 14.01 ± 12.944 |
| **Fluid delivered via the study catheter (mL)** | | | |
| n | 154 | 52 | 102 |
| Mean ± SD | 546.5 ± 298.55 | 434.4 ± 190.79 | 603.7 ± 326.90 |
| **Fluid delivered via intravenous fluids (mL)** | | | |
| n | 159 | 56 | 103 |
| Mean ± SD | 861.2 ± 557.28 | 744.5 ± 472.39 | 924.7 ± 590.93 |

**Table 11 – Number of RF Applications, Average Duration of RF Application and Average Contact Force per Ablation Procedure (Per-Protocol Analysis Set, N=166)**

| Variable | QMODE+ Only n=59 | QMODE+ and QMODE Combined n=107 |
|---|---|---|
| **Number of RF Applications** | | |
| Mean ± SD | 100.5 ± 39.36 | 132.7 ± 41.80 |
| **Average Duration of RF Application (sec)*** | | |
| Mean ± SD | 3.870 ± 0.0393 | 7.384 ± 4.5099 |
| **Average Contact Force (g)** | | |
| Mean ± SD | 15.800 ± 5.3346 | 15.194 ± 5.1492 |

* Applications with RF energy >0 W and duration of RF application ≥1 sec were included for analysis.

**Ablation Targets**

Table 12 summarizes ablation targets. As required by the protocol, PVs were targeted in all index procedures. Among the PP analysis set, about 40% of the subjects received ablations beyond PVI.

**Table 12 – Ablation Sites Targeted (Per-Protocol Analysis Set, N=166)**

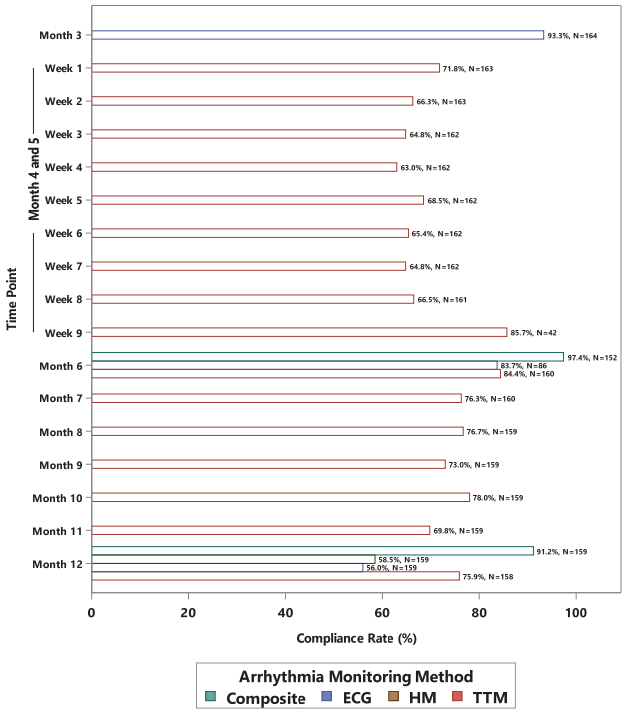
| Ablation Sites Targeted | Number of Subjects |
|---|---|
| **Total** | 166 |
| **PVI only** | 100 / 166 (60.2%) |
| **Non-PV** | 66 / 166 (39.8%) |
| Roof line | 16 / 66 (24.2%) |
| Cavo-tricuspid isthmus | 46 / 66 (69.7%) |
| Other linear lesion | 15 / 66 (22.7%) |
| Other AF foci | 16 / 66 (24.2%) |
| Other | 3 / 66 (4.5%) |

C.4 - Rhythm Monitoring Compliance

During the 9-month evaluation period, rhythm monitoring included symptomatic and scheduled asymptomatic TTM transmissions (weekly from Month 3 visit through Month 5 post ablation and monthly starting from Month 6 to Month 12), 12-lead ECG at 3 and 12 months and at 6 months if subject returned for an in-clinic visit, and 24-hour Holter at Month 12.

Figure 1 shows the TTM, 12-lead ECG, and Holter compliance rates at each evaluation time point in the Per-Protocol Analysis Set. The overall TTM and Holter compliance rates were 70.3% and 58.5%, respectively. The ECG compliance rate was 93.3%, 83.7%, and 56.0% at Month 3, 6, and 12, respectively. The composite compliance rate was 97.4% and 91.2% at Month 6 and Month 12, respectively, where at least two rhythm monitoring methods were required per protocol.

**Figure 1 – TTM/ECG/HM Compliance by Time Point (Per-Protocol Analysis Set, N=166)**




## C.5 - Safety Results

### C.5.1 - Primary Safety Endpoint

*Primary Analysis*

The primary safety endpoint for this study was defined as the incidence of early onset Primary AEs for subjects undergoing a study ablation procedure. Per study protocol, the primary safety analysis was based on primary safety event rate using the mITT analysis set (N=166) as the primary analysis population.

Table 13 displays a summary for the primary safety endpoint in subjects with non-missing outcomes in the mITT analysis set. The raw incidence was 3.6%. The posterior mean of PAE rate was 4.2%, with a 95% Bayesian credible interval (BCI) ranging from 1.7% to 7.7%. This is well below the performance goal of 14%. The posterior probability that the PAE rate less than the performance goal of 0.14 was close to 1.0000 (i.e., > 0.99995), which exceeded the early success threshold of 0.975. The study met the early success threshold for the primary safety endpoint. There were no changes to the primary safety endpoint data between the early success interim analysis and the final analysis.

**Table 13 – Summary of Primary Safety Endpoint Analysis (mITT Analysis Set, N=167)**

| | |
|---|---|
| Subjects with Primary Safety Events | 6 |
| Subjects without Primary Safety Events | 160 |
| Missing | 1 |
| Raw Incidence | 3.6% |
| Posterior Mean* | 4.2% |
| 95% BCI | (1.7%, 7.7%) |
| Posterior Probability* that rate < 0.14 | 1.0000 |
| Threshold to Pass | 0.9750 |
| Pass? | Yes |

* Using Beta (1,1) prior distribution

Table 14 presents the descriptive summaries by type of primary adverse events, which were adjudicated by CEC. The PAEs reported in this study were as follows: Three (3) major vascular access complication/bleeding events (reported in 3 subjects, 1.8%), two (2) cardiac tamponade/perforation events (2 subjects, 1.2%), and two (2) phrenic nerve injury/diaphragmatic paralysis events (1 subject, 0.6%). Both cardiac tamponade/perforation events required pericardiocentesis and one of them required blood transfusion; both were adjudicated as procedure related and possibly device related. The three (3) major vascular access complications were adjudicated as procedure related and included one femoral artery pseudoaneurysm requiring thrombin injection, one retroperitoneal bleed and one arteriovenous fistula. The events of phrenic nerve injury/diaphragmatic paralysis were adjudicated as both device and procedure related.

The subject adjudicated by CEC as phrenic nerve injury/diaphragmatic paralysis was re-evaluated at the 12-month visit to determine if the phrenic nerve injury is permanent and was deemed non-assessable by CEC. The sponsor has conservatively counted the adverse event as a PAE.

**Table 14 – Primary Safety Endpoint Outcome – Primary AEs (mITT Analysis Set, N=167)**

| Variable | Number of Subjects with Event | Number of Events | Event Rate n/N (%) [1] |
|---|---|---|---|
| **Primary Adverse Event** | 6 | 7 | 6 / 166 (3.6%) |
| **Type of Primary Adverse Event** | | | |
| Death (Device or procedure related) | 0 | 0 | 0 / 166 (0.0%) |
| Atrio-Esophageal Fistula | 0 | 0 | 0 / 166 (0.0%) |
| Cardiac Tamponade/Perforation | 2 | 2 | 2 / 166 (1.2%) |
| Myocardial Infarction | 0 | 0 | 0 / 166 (0.0%) |
| Stroke/Cardiovascular Accident (CVA) | 0 | 0 | 0 / 166 (0.0%) |
| Thromboembolism | 0 | 0 | 0 / 166 (0.0%) |
| Transient ischemic Attack (TIA) | 0 | 0 | 0 / 166 (0.0%) |
| Phrenic Nerve Injury / Diaphragmatic Paralysis | 1 | 2 | 1 / 166 (0.6%) |
| Heart Block | 0 | 0 | 0 / 166 (0.0%) |
| Pulmonary Vein Stenosis | 0 | 0 | 0 / 166 (0.0%) |
| Pulmonary Edema (Respiratory Insufficiency) | 0 | 0 | 0 / 166 (0.0%) |
| Vagal Nerve Injury | 0 | 0 | 0 / 166 (0.0%) |
| Pericarditis | 0 | 0 | 0 / 166 (0.0%) |
| Major Vascular Access Complication / Bleeding | 3 | 3* | 3 / 166 (1.8%) |

[1] One subject did not experience a PAE and exited the study prior to 3-month follow-up visit; subject was excluded from this analysis.

* Major vascular access complication/bleeding events included one retroperitoneal hemorrhage, one vascular access site hemorrhage and one pseudoaneurysm.

*Sensitivity Analysis*

The primary safety endpoint was also analyzed in the Safety Analysis set because it is considered by the FDA as a more clinically relevant analysis population for device safety evaluation. Of the 176 subjects in the Safety analysis set, 10 underwent the study ablation procedure and had the study catheter inserted but were identified post-procedure to not meet eligibility criteria for the study. These subjects were not included in the mITT analysis set but were included in the Safety analysis set. No PAEs were reported in these 10 subjects. One (1) subject withdrew from the study 48 days post the index procedure with no PAE, was considered missing and excluded from this analysis.

As summarized in Table 15, the rate of PAE was 3.4% (6/176) in the safety analysis set. The posterior mean of the PAE rate was 3.9%, with an 95% BCI ranging from 1.6% to 7.2%. With 10 more subjects in the analysis, the posterior probability of the PAE rate being less than 0.14 remain greater than 0.9999 which is well above the threshold of 0.975.

**Table 15 – Summary of Primary Safety Endpoint Analysis (Safety Analysis Set, N=177)**

| | |
|---|---|
| Subjects with Primary Safety Events | 6 |
| Subjects without Primary Safety Events | 170 |
| Missing | 1 |
| Raw Incidence | 3.4% |
| Posterior Mean* | 3.9% |
| 95% BCI* | (1.6%, 7.2%) |
| Posterior Probability* that rate < 0.14 | 1.0000 |
| Threshold to Pass | 0.9750 |

* Using Beta (1,1) prior distribution

C.5.2 - Incidence of UADEs

There were no UADEs reported in the study.

C.5.3 - Incidence of Early Onset, Peri-Procedural and Late Onset SAEs

Table 16 Summaries the incidence of early onset, peri-procedural and late onset SAEs in the Safety Analysis set.

**Table 16 – Serious Adverse Events by Timing of Onset (Safety Analysis Set, N=177)**

| Serious Adverse Events - by Timing of Onset [1] | Number of Events | Number of Subjects with Event | Event Rate [2] n/N (%) |
|---|---|---|---|
| **Total** | 55 | 34 | |
| 0 - 7 Days | 14 | 12 | 12 / 177 (6.8%) |
| 8 - 30 Days | 5 | 4 | 4 / 177 (2.3%) |
| > = 31 Days | 36 | 25 | 25 / 177 (14.1%) |

Note: This table summarizes all SAEs. Adjudication for seriousness is based on CEC for PAEs or site for non-PAEs.

[1] Including events on and after the day of procedure. Timing of AE based on onset in days post procedure (index or repeat).

[2] N denotes number of subjects with follow-up duration corresponding to each time interval.

Table 17 summarizes the SAEs (by causality and body system) occurring within 30 days of a study ablation procedure that were not classified as Primary AEs by protocol definition.

**Table 17 – Serious Non-Primary AEs Occurring within 30 Days Post Index/Repeat Ablation Procedure) by Causality and Body System (Safety Analysis Set, N=177)**

| Relationship to the Device/Procedure by Body System | Number of Subjects with Event | Number of Events [1] | Event Rate [2] |
|---|---|---|---|
| **Overall** | 11 | 13 | 11 / 177 (6.2%) |
| | | | |
| **Causal Relationship to Device** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |

| Relationship to the Device/Procedure by Body System | Number of Subjects with Event | Number of Events [1] | Event Rate [2] |
|---|---|---|---|
| **Probable Device Related** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |
| **Possible Device Related** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |
| **Unlikely Device Related** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |
| **Not Device Related** | 11 | 13 | 11 / 177 (6.2%) |
| Cardiac disorders | 7 | 8 | 7 / 177 (4.0%) |
| Atrial fibrillation | 3 | 3 | 3 / 177 (1.7%) |
| Atrial flutter | 2 | 2 | 2 / 177 (1.1%) |
| Congestive Cardiac failure | 1 | 1 | 1 / 177 (0.6%) |
| Cardiac tamponade | 1 | 1 | 1 / 177 (0.6%) |
| Pericardial effusion | 1 | 1 | 1 / 177 (0.6%) |
| General disorders and administration site conditions | 3 | 3 | 3 / 177 (1.7%) |
| Chest pain | 2 | 2 | 2 / 177 (1.1%) |
| Pyrexia | 1 | 1 | 1 / 177 (0.6%) |
| Respiratory, thoracic and mediastinal disorders | 1 | 1 | 1 / 177 (0.6%) |
| Pulmonary embolism | 1 | 1 | 1 / 177 (0.6%) |
| Vascular disorders | 1 | 1 | 1 / 177 (0.6%) |
| Arteriovenous fistula | 1 | 1 | 1 / 177 (0.6%) |
| | | | |
| **Causal Relationship to Procedure** | 1 | 1 | 1 / 177 (0.6%) |
| General disorders and administration site conditions | 1 | 1 | 1 / 177 (0.6%) |
| Chest pain | 1 | 1 | 1 / 177 (0.6%) |
| | | | |
| **Probable Procedure Related** | 3 | 5 | 3 / 177 (1.7%) |
| Cardiac disorders | 2 | 3 | 2 / 177 (1.1%) |
| Congestive Cardiac failure | 1 | 1 | 1 / 177 (0.6%) |
| Cardiac tamponade | 1 | 1 | 1 / 177 (0.6%) |
| Pericardial effusion | 1 | 1 | 1 / 177 (0.6%) |
| Respiratory, thoracic and mediastinal disorders | 1 | 1 | 1 / 177 (0.6%) |
| Pulmonary embolism | 1 | 1 | 1 / 177 (0.6%) |
| Vascular disorders | 1 | 1 | 1 / 177 (0.6%) |
| Arteriovenous fistula | 1 | 1 | 1 / 177 (0.6%) |
| | | | |
| **Possible Procedure Related** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |
| **Unlikely Procedure Related** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |

| Relationship to the Device/Procedure by Body System | Number of Subjects with Event | Number of Events [1] | Event Rate [2] |
|---|---|---|---|
| **Not Procedure Related** | 7 | 7 | 7 / 177 (4.0%) |
| Cardiac disorders | 5 | 5 | 5 / 177 (2.8%) |
| Atrial fibrillation | 3 | 3 | 3 / 177 (1.7%) |
| Atrial flutter | 2 | 2 | 2 / 177 (1.1%) |
| General disorders and administration site conditions | 2 | 2 | 2 / 177 (1.1%) |
| Chest pain | 1 | 1 | 1 / 177 (0.6%) |
| Pyrexia | 1 | 1 | 1 / 177 (0.6%) |

[1] Timing of AE based on onset in days post the procedure (index or repeat).

[2] Event rate is the percentage of subjects with the event.

C.5.4 - Subject Death

There was one (1) death during the study. The subject was a 66-year-old male with history of PAF and multiple comorbidities (coronary artery disease, hypertension, non-ischemic cardiomyopathy, congestive heart failure, status post-biventricular pacer for cardiac resynchronization therapy). He underwent the study procedure without immediate complications. Five months following the ablation procedure, the subject suffered a witnessed cardiac arrest due to ventricular fibrillation and was resuscitated by immediate cardiopulmonary resuscitation and external defibrillations 10 minutes after the onset of ventricular fibrillation. He subsequently suffered from anoxic brain injury and pneumonia without clinical improvement after therapy. The subject expired about 7 months post ablation. The death was classified as not related to the procedure or the device by the investigator.

C.5.5 - CT/MRA Sub-Set Analysis

Table 18 presents the results of the CT/MRA subset analysis. A total of 40 subjects in the CT/MRA subset underwent the CT/MRA imaging of the PVs pre-procedure and 3 months post-procedure. No subjects showed moderate or severe pulmonary vein stenosis in the subset.

**Table 18 – PV Narrowing Post Ablation (CT/MRA Analysis Set, N=40)**

| Pulmonary Vein Stenosis | | Mild | | Moderate | Severe |
|---|---|---|---|---|---|
| | **Less than 0%** | **0-20%** | **20-50%** | **50-70%** | **> 70%** |
| Subject-Level Summary, n/N (%) | 1 / 40 (2.5%) | 15 / 40 (37.5%) | 24 / 40 (60.0%) | 0 / 40 (0.0%) | 0 / 40 (0.0%) |

C.6 - Effectiveness Results

C.6.1 - Primary Effectiveness Endpoint

*Primary Analysis*

Per study protocol, the primary effectiveness analysis was based on primary effectiveness success using the PP Analysis Set as the primary analysis population.

An early success interim analysis was performed as pre-specified in the protocol with a data extract obtained on June 22nd, 2020 and repeated after the endpoint was met with an additional data extract obtained on August 14th, 2020 to incorporate FDA feedback.

At the planned interim analysis, the posterior mean of event-free rate at Month 12 was 74.5%, with a 95% Bayesian credible interval (BCI) ranging from 66.6% to 81.5%. The posterior probability that the

event-free rate at Month 12 was greater than the performance goal of 50% was close to 1.0000 (i.e., 0.99995), which exceeded the pre-specified threshold of 0.9975. The primary effectiveness endpoint was therefore met at the early success interim analysis.

The analysis of the primary effectiveness endpoint on the August 14, 2020 data extract yielded similar results. These results have been updated with complete follow-up on the full cohort using a beta-binomial model with a non-informative prior. The final primary effectiveness rate is nearly identical to the interim estimate.

Table 19 presents the primary effectiveness analysis based on interim analysis and final analysis in the PP Analysis set.

**Table 19 – Summary of Primary Effectiveness Endpoint Analysis based on the Interim Analysis and Final Analysis (Per-Protocol Analysis Set, N=166)**

| | Jun-22, 2020 Data | Aug-14, 2020 Data | Final Data |
|---|---|---|---|
| | **Based on 3-piece exponential model** | **Based on 3-piece exponential model** | **Based on Beta-Binomial Model** |
| **Kaplan-Meier Estimate (39 weeks)** | 0.765 | 0.778 | 0.767 |
| **Posterior Mean** | 0.745 | 0.755 | 0.759 |
| **95% BCI** | (0.666, 0.815) | (0.684, 0.820) | (0.690, 0.823) |
| **Posterior Probability that $P_E$ > 0.50** | 1.0000 | 1.0000 | 1.0000 |
| **Threshold to Pass** | 0.9975 | 0.9975 | |
| **Pass** | Yes | Yes | |

The first failure reason for subjects in the Per-Protocol analysis set is presented in Table 20. Ten (10) subjects with missing effectiveness outcomes are excluded from the summary. Approximately seventy six percent (76.3%, 119/156) of the Per-Protocol population were free from documented atrial tachyarrhythmias and additional failure modes during their effectiveness evaluation period. Documented recurrence of atrial tachyarrhythmias (17.3%, 27/156) and repeat ablation failures (2.6%, 4/156) were the most common reasons for first failure.

**Table 20 – Primary Effectiveness Endpoint by Reason of The First Failure (Per-Protocol Analysis Set, N=166)**

| Variable | Number of Subjects with Event | Event Rate n/N (%) [1] |
|---|---|---|
| Success | 119 | 119/156 (76.3%) |
| First Failures [2] | 37 | 37/156 (23.7%) |
| Atrial Tachyarrhythmia Recurrence | 27 | 27/156 (17.3%) |
| AF | 25 | 25/156 (16.0%) |
| AFL | 2 | 2/156 (1.3%) |
| AT | 0 | 0/156 (0.0%) |
| Acute Procedural Failure | 3 | 3/156 (1.9%) |
| Acute Procedural Failure - Non-study Catheter | 3 | 3/156 (1.9%) |
| Acute Procedural Failure - Entrance Block | 0 | 0/156 (0.0%) |
| Repeat Ablation | 4 | 4/156 (2.6%) |
| AAD Failure | 3 | 3/156 (1.9%) |
| AAD Failure - New Drug | 3 | 3/156 (1.9%) |

| Variable | Number of Subjects with Event | Event Rate n/N (%) [1] |
|---|---|---|
| AAD Failure - High Dose | 0 | 0/156 (0.0%) |
| Missing | 10 | |

[1] N is the number of subjects with non-missing primary effectiveness endpoint.

[2] First failures: If a subject has at least 1 failure event, only the earliest failure event is considered and ed by its failure mode.

*Sensitivity Analysis*

Sensitivity to Analysis Sets

Table 21 presents the posterior means of event-free rate at Month 12 using the beta binomial model in the mITT, Safety and Treatment Received Analysis Sets based on the final full follow up data. The Treatment Received Analysis Set was included in the sensitivity analyses per FDA's feedback because it is considered by the FDA as the most clinically relevant analysis population for device effectiveness evaluation. The results suggested that the success rates in all three Analysis Sets met the effectiveness performance goal. Of note, of the two (2) discontinued subjects who had the study catheter inserted but received no RF ablation from the device, one was not included in the mITT Analysis Set due to study eligibility criteria violation, both were included in the Safety Analysis Set and neither was included in the Treatment Received Analysis Set. Both discontinued subjects were classified as primary effectiveness failures due to use of a non-study catheter for PVI in the respective analysis population.

**Table 21 – Primary Effectiveness Endpoint in mITT, Safety and Treatment Received Analysis Sets**

| | mITT Analysis Set (N=167) | Safety Analysis Set (n = 177) | Treatment Received Analysis Set (n = 175) |
|---|---|---|---|
| **Posterior Mean** | 0.755 | 0.746 | 0.754 |
| **95% BCI** | (0.685, 0.818) | (0.678, 0.808) | (0.687, 0.817) |

Kaplan-Meier analysis

Figures Figure 2 and Figure 3 present Kaplan-Meier freedom from effectiveness failure for subjects in the Per-Protocol Analysis Set and Treatment Received Analysis Set, respectively. The 12-month Kaplan-Meier estimate of freedom from effectiveness failure was 76.7% (97.5% LCB: 70.1%) in the Per-Protocol Analysis Set and 76.2% (97.5% LCB: 69.7%) in the Treatment Received Analysis Set, both of which are comparable to the posterior mean of 75.9% from the final data.

**Figure 2 – Kaplan-Meier Analysis of Time to First Primary Effectiveness Failures Post Procedure (Per-Protocol Analysis Set, N=166)**

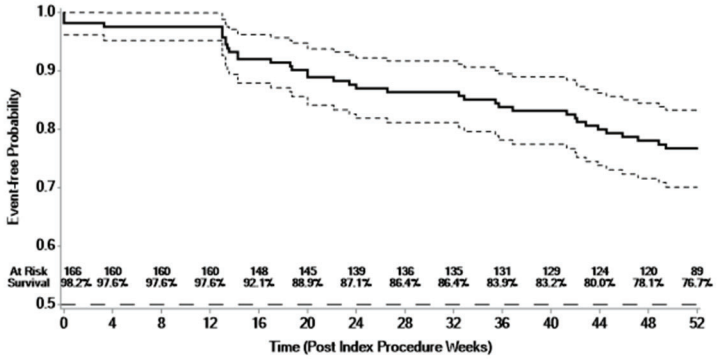
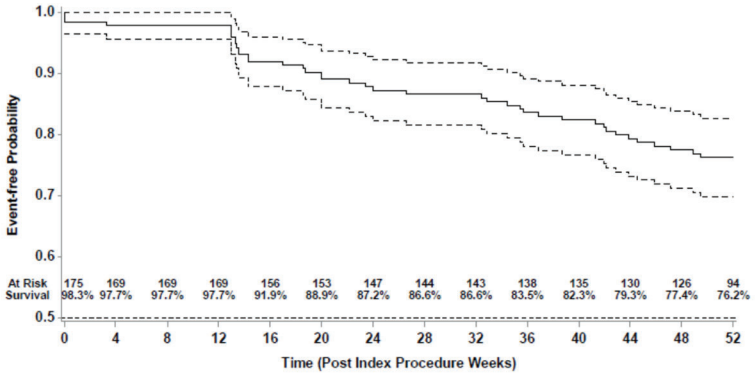


**Figure 3 – Kaplan-Meier Analysis of Time to First Primary Effectiveness Failures Post Procedure (Treatment Received Analysis Set, N = 175)**




Worst-case scenario and tipping point analyses

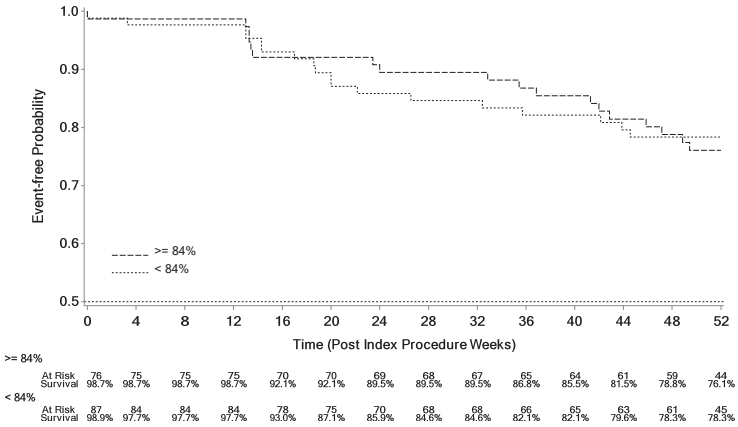
In the worst-case scenario analysis, the 10 subjects missing primary effectiveness endpoint data were considered as having primary effectiveness failure, which resulted in the primary effectiveness success rate of 71.7% in the Per-Protocol Analysis Set, 71.3% in the mITT analysis set and 71.4% in Treatment Received Analysis Set.

Treating all of the 10 subjects with missing outcomes as effectiveness failures one by one, tipping point analyses using a posterior probability threshold of 0.9775 were performed for the primary effectiveness endpoint in the PP, mITT and Treatment Received Analysis Sets to assess the impact of missing outcomes on the primary effectiveness analysis. The posterior distribution was updated each time and the results showed that no tipping point was identified. Therefore, the primary effectiveness performance goal was met in the tipping point analysis.

*Impact of TTM Compliance*

To better understand the impact of TTM compliance on the primary effectiveness results, additional post-hoc Kaplan-Meier analysis on the time to first primary effectiveness failure was performed in subgroups dichotomized at TTM compliance of 84%, a compliance rate reported in a previous PAF ablation trial. The probability of freedom from primary effectiveness failures at 12 months was similar between subjects with TTM compliance rate of < 84% and those ≥ 84% (Figure 4).

**Figure 4 – Kaplan-Meier Analysis of Time to Primary Effectiveness Failures Post Procedure by TTM Compliance (>= 84% vs. <84%) (Per-Protocol Analysis Set, N=166)**




C.6.2 - Acute Procedural Success

Acute procedural success was defined as confirmation of entrance block in all PVs. Off the 166 subjects included in the PP analysis set, two (2) subjects were treated with a non-study catheter for PVI due to CoolFlow Pump malfunction which resulted in replacement of the QDOT catheter with a non-study catheter to complete PVI. These two (2) subjects were excluded from the analysis of acute

procedural success. Acute procedural success was achieved in the remaining 164 subjects (100%, 97.5% LCB: 97.8%) in the PP Analysis Set.

Table 22 presents data on PVI after first encirclement at subject level and at ipsilateral PV level, respectively. Among a total of 164 subjects in the PP Analysis Set who received PVI ablation using the study catheter only (two subjects also treated with a non-study catheter for PVI and discussed above were excluded from the analysis), 94 (57.3%) achieved PVI with first encirclement without acute reconnections. For this analysis, both right-sided PVs and left-sided PVs for the subject had to achieve PVI without acute reconnections. At ipsilateral PV level, PVI was achieved in 72.6% (238/328) of the pulmonary veins (ipsilateral veins) after first encirclement without acute reconnections.

**Table 22 – PVI after First Encirclement at Subject Level and at Ipsilateral PV level (Per-Protocol Subjects Who Received PVI Ablation Using the Study Catheter Only, N=164)**

| Variable | Number of Subjects Underwent Ablation Procedure | Number of Subjects | Rate |
|---|---|---|---|
| PVI after first encirclement | 164 | 94 | 94 / 164 (57.3%) |
| **Variable** | **Number of Targeted Ipsilateral Veins** | **Number of Targeted Ipsilateral Veins with first encirclement** | **Rate** |
| PVI after first encirclement | 328 | 238 | 238 / 328 (72.6%) |

C.6.3. - Incidence of repeat ablation procedures

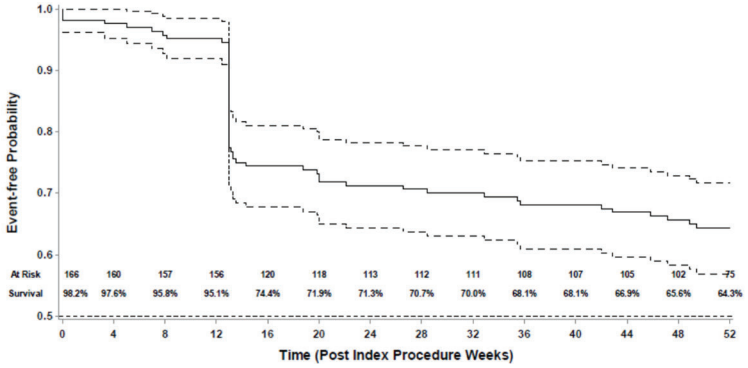
A total of 18 subjects (10.8%) in the Per-Protocol analysis set had one (1) repeat procedure and most (66.7%, 12/18) had their repeat procedure during the evaluation period (Day 91-365). Most subjects (88.9%, 16/18) were treated for AF during the repeat procedure.

C.6.4. - 12-month single procedure success

The 12-Month single procedure success was defined as freedom from documented AF/AFL/AT recurrence (episodes ≥ 30 secs) during the evaluation period after a single ablation and off AADs. Any repeat ablation procedure or Class I or III AAD use for AF/AFL/AT during the evaluation period was deemed effectiveness failure for this endpoint analysis.

Figure 5 presents the Kaplan- Meier analysis of 12-Month single procedure success off Class I/III AAD in the Per Protocol analysis set. The probability of 12-Month single procedure success off Class I/III AADs post blanking was 64.3% in the Per-Protocol analysis set.

**Figure 5 – 12-Month Single Procedure Success off Class I/IIIAADs Post Blanking (Per Protocol Analysis Set, N=166)**



C.6.5 - Quality of Life

The quality of life was measured using the Atrial Fibrillation Effect on Quality-of-Life (AFEQT) at baseline and the 3-, 6-, and 12-month visits.

Figure 6 presents the mean AFEQT composite scores at baseline, 3-, 6-, and 12-month follow up visits in the effectiveness evaluation period, indicating a sustained improvement on the AFEQT scores from 3 months to 12 months post ablation.

**Figure 6 – Mean AFEQT Composite Scores Throughout Study Period (Per-protocol Analysis Set, N=166)**

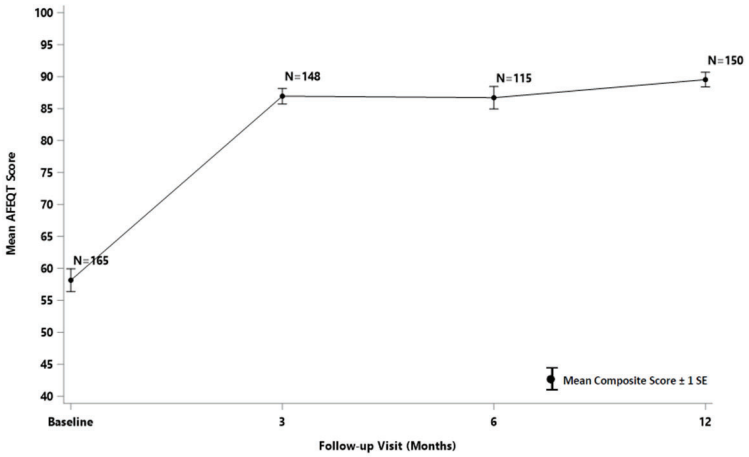
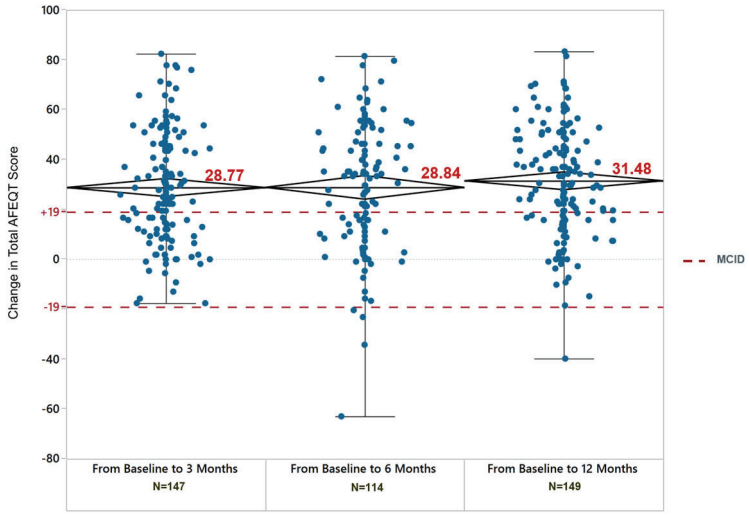



Figure 7 presents change in total AFEQT scores from baseline at 3, 6, and 12 months. The mean change of AFEQT score from baseline to 3 months (28.77) was sustained at 12 months (31.48) and was larger than a clinical important difference of 19 (Dorian et al., 2013) in the majority of subjects.

**Figure 7 – Atrial Fibrillation Effect on Quality of Life (AFEQT) Questionnaire Overall AFEQT Score (Per-Protocol Analysis Set, N=166)**




C.7 - Subgroup Analyses

Subgroup analyses for the primary endpoints were performed , including but not limited to: sex, age,

CHA2DS2-VASc score, and ablation mode used for PVI. Per protocol, a test of independence by sex was performed for both primary endpoints, while for other subgroup analyses only descriptive statistics were presented. The PP Analysis Set and Safety Analysis Set were used for the subgroup analyses of the primary effectiveness endpoint and primary safety endpoint, respectively. The primary effectiveness success rates were similar by age (< 65 vs. ≥ 65 years) and CHA2DS2-VASc score (<=2 vs. >2).

i Gender analysis

The primary endpoints were assessed according to gender. Tables Table 23 and Table 24 summarize the primary effectiveness and safety endpoints by sex in the PP and Safety Analysis Sets, respectively. Effectiveness and safety outcomes were similar between male and female subjects.

**Table 23 – Primary Effectiveness Endpoint by Sex (Per-Protocol Analysis Set, N=166)**

| Primary Effectiveness Endpoint | Male | Female | p-value [1] |
|---|---|---|---|
| Primary Effectiveness Endpoint Success | | | 0.329 |
| n/N | 75 / 95 | 44 / 61 | |
| % | 78.9% | 72.1% | |

[1] Chi-square test

**Table 24 – Primary Safety Endpoint by Sex (Safety Analysis Set, N=177)**

| Primary Safety Endpoint | Male | Female | p-value [1] |
|---|---|---|---|
| Primary AE | | | 0.683 |
| n/N | 3 / 106 | 3 / 70 | |
| % | 2.8% | 4.3% | |

[1] Fisher's exact test

ii Primary Safety by Age (<65 vs. ≥=65)

Table 25 summarizes the primary safety endpoint by age in the Safety Analysis Set. No PAEs were observed in subjects aged <65 years. All PAEs occurred in subjects who were aged ≥65 years. The big difference in the primary safety event rate between the two age groups was likely caused by chance in the study in which a very small number of primary safety events occurred. Previous AF ablation studies (Hao, et al., 2012 and Zado, et al., 2008) reported comparable major complication rates between patients 65 years of age or older and those under age 65.

**Table 25 – Primary Safety Endpoint by Age (Safety Analysis Set, N=177)**

| Primary Safety Endpoint | Age < 65 years | Age ≥ 65 years |
|---|---|---|
| n/N | 0 / 82 | 6 / 94 |
| % | 0.0% | 6.4% |

iii Subgroup analysis of primary endpoints by ablation mode used for PV isolation

Primary effectiveness success was evaluated by ablation mode used for isolating the PVs. Figure 8 presents the Kaplan- Meier analysis of time to primary effectiveness failures by ablation mode used for PVI in the PP Analysis Set. The probabilities of freedom from primary effectiveness failure at 12 months post-procedure were comparable in the 2 groups, QMODE+ for PVI (78.1%) vs. QMODE+ and QMODE for PVI (75.1%).

**Figure 8 – Kaplan-Meier Analysis of Time to First AF/AT/AFL Recurrence Through 12 Months Post Procedure by PV Ablation Mode (Per-Protocol Analysis Set, N=166)**

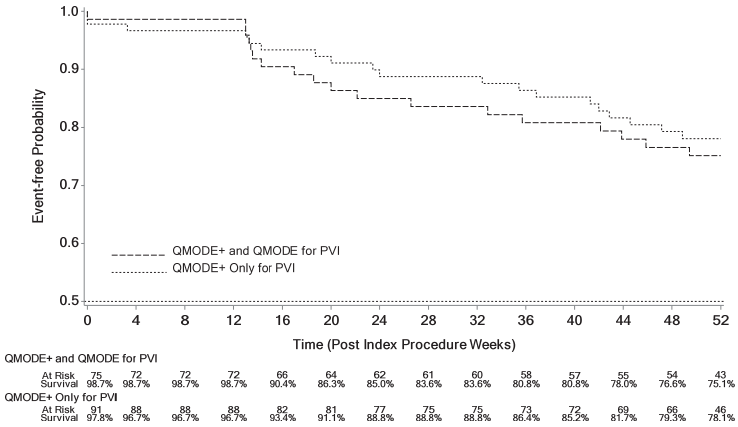



Table 26 summarizes the primary safety outcome by ablation mode used for PVI in the Safety Analysis Set. The PAE rate was similar between the QMODE+ only group and QMODE+ and QMODE group.

**Table 26 – Primary Safety Endpoint by PV Ablation Mode (Safety Analysis Set, N=177)**

| Primary Safety Endpoint | QMODE+ Only | QMODE+ and QMODE |
|---|---|---|
| Primary AE | | |
| n/N | 3 / 95 | 3 / 79 |
| % [1] | 3.2% | 3.8% |

[1] The percentage of subjects with PAEs within each group. Subjects without at least 3 months of follow-up are excluded from the primary safety analysis unless they experienced a PAE.

C.8 - Results in Subjects Who Received Cavo-tricuspid Isthmus Ablation Using Study Catheter

Among a total of 175 subjects who received RF ablation using the study device in the pivotal trial, 47 underwent CTI ablation using the study device only (n = 45), a non-study catheter only (n = 1), or both (n = 1)during the index procedure per study protocol for typical atrial flutter documented either before or during the procedure. Protocol recommended QMODE mode was used to ablate the CTI in all 33 subjects with ablation mode data available and one of the 33 subjects also received ablations in the CTI using the QMODE+ mode.

Among the 46 subjects who received CTI ablation using the study catheter, 44 (95.7%) had bidirectional CTI block confirmed, and the remaining two subjects either did not achieve bidirectional CTI block (n=1) or had missing information about CTI block (n = 1).

Among the 46 subjects who received CTI ablation using the study catheter, none had a primary AE, three (3) had a total of three (3) serious adverse events and 11 had a total of 12 non-serious adverse events within 30 days after a study procedure. None of these serious adverse events or non-serious adverse events was adjudicated as study device-related; while 9 non-serious adverse events were adjudicated as ablation procedure related.

Among the 46 subjects who received CTI ablation using the study catheter, two (2) had documented atrial flutter recurrence during follow-up. The type of recurrent atrial flutter was atypical atrial flutter in one subject and undetermined in another because it was only documented on TTM.

## D. Study Conclusion

The results of the Q-FFICIENCY study demonstrated that there is a reasonable assurance of safety and effectiveness of the QDOT MICRO™ Catheter when used for the treatment of symptomatic drug refractory paroxysmal AF and typical atrial flutter.

## RF ABLATION

For RF ablation the catheter is connected to the CARTO™ 3 System Patient Interface Unit (PIU) via accessory cables, which connect to the RF generator. For setup procedures refer to the User Manual for your CARTO™ 3 Navigation System. For proper RF generator interface, use only a Biosense Webster or compatible interface cable. To complete the electrical circuit, an indifferent electrode must be connected to the indifferent electrode input on the RF generator. Verify that circuit impedance prior to RF ablation is within expected parameters. Verify that the RF generator displays a temperature not above 37°C after the catheter is inserted into the patient and before applying RF power.

## RF GENERATOR OPERATION

Refer to the applicable RF generator manual for proper connection of the catheter to the generator and for detailed instructions as to generator operation for RF ablation.

RF ablation application parameters will vary depending on the ablation site, the specific conditions present in each procedure and the RF generator control circuitry. Based on data obtained from prior animal and clinical studies, recommended RF application parameters are provided below in the “Directions for Use” and in Table 1. Always monitor temperature and impedance rise when using the QDOT MICRO™ Uni-Directional Navigation Catheter.

## HOW SUPPLIED

- The QDOT MICRO™ Uni-Directional Navigation Catheter is supplied STERILE (EtO).
- The catheter is supplied with a choice of three curve configurations: “D”, “F”, and “J”.
- Additional catheter accessory devices are provided separately.

## PACKAGING

The catheter is secured in a one-piece thermoform tray and placed into a Tyvek/Nylon film pouch, sealed and placed in a unit carton. The sealed pouch forms the sterile barrier. Both the interior of the pouch and the thermoform tray are sterile unless the package is damaged or opened. The pouch and unit carton are labeled to indicate that the device contained within is sterile.

## STORAGE

Store in a cool, dry, dark place. Storage temperature should be between 5 and 25°C (41 and 77°F).

## STERILIZATION AND USE-BY DATE

This catheter has been sterilized with ethylene oxide gas. Product and package testing have been conducted to support the “Use By” date printed on the product labels. **DO NOT USE** after the “Use By” date.

This device is packaged and sterilized for single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness, or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

## DISPOSAL

Recycle components, or dispose of the product and its residual elements or waste items in accordance with local laws and regulations.

## COMPATIBLE EP NAVIGATION SYSTEM

The Biosense Webster QDOT MICRO™ Uni-Directional Navigation Catheter provides location and contact force information only when used with CARTO™ 3 Navigation System. Compatibility with the CARTO™ 3 System has been demonstrated via bench, animal, and clinical testing to confirm that the device is capable of providing accurate location and contact force information when used in accordance with the Instructions for Use.

## DIRECTIONS FOR USE

Please refer to the user manuals for the CARTO™ 3 Navigation System, the irrigation pump, the irrigation tubing, and the generator for instructions on connecting and operating these systems in conjunction with the QDOT MICRO™ Uni-Directional Catheter. Use appropriate Biosense Webster accessory cables to connect the QDOT MICRO™ Uni-Directional Catheter to the appropriate accessory equipment.

1. Using aseptic technique, remove the catheter from the package and place it in a sterile work area. Inspect the catheter carefully for electrode integrity and overall condition.
2. The catheter tip can be deflected to facilitate positioning by using the thumb knob to vary tip curvature. Pushing the thumb knob forward causes the catheter tip to deflect. When the thumb knob is pulled back, the tip straightens.
3. Follow standard practice for vessel puncture, guidewire insertion, and guiding sheath use and aspiration per its instructions for use.
4. To verify compatibility between the sheath and catheter, advance the catheter through the sheath prior to insertion. Any sheath < 8.5 F is contraindicated. For compatible sheaths, contact Customer Support or your Biosense Webster representative.
5. Connect the irrigation pump tubing to a room temperature, heparinized (1 IU heparin/ml) normal saline bag using standard safe hospital practices. Open the stopcock on the end of the tubing set and fill the tubing set as slowly as possible. Remove any trapped air and then close the stopcock.
6. Load the irrigation tubing into the pump. Open the stopcock and flush per the irrigation pump instructions until the air is expelled through the open end of the tubing.
7. Connect the irrigation tubing to the Luer fitting of the catheter.
8. Flush the catheter and tubing to ensure purging of trapped air bubbles and to verify irrigation through the tip electrode.
9. Start continuous irrigation with the irrigation pump at the low flow rate.
10. Connect the catheter to the CARTO™ System Patient Interface Unit (PIU) with the appropriate Biosense Webster cables. Connect the PIU to the generator and to the appropriate recording and mapping systems, including the CARTO™ 3 Navigation System, with appropriate interface cables. Use only Biosense Webster interface cables. To complete the electrical circuit, connect an indifferent electrode to the indifferent electrode input on the generator.
11. Insert the QDOT MICRO™ Uni-Directional Catheter via the entrance site.
12. Advance the catheter to the desired area. Use both direct imaging guidance (such as fluoroscopy or ultrasound) and electrograms (EGM) to aid in proper positioning.
13. In order to achieve optimal force reading accuracy and stability, allow the catheter to warm up for 2 minutes after connection to the CARTO™ 3 System, prior to use of the force feedback feature.
14. Zero the contact force reading following insertion into the patient. The tip electrode and the two distal ring electrodes on the catheter tip must be outside of the sheath so that the force sensor is inside the body. Ensure the catheter tip is not in contact with tissue by evaluating the location on fluoroscopy, the CARTO™ System or other direct imaging guidance along with the EGM amplitude and catheter movement. Variations in the force reading at the same rate as the cardiac or respiration cycle may indicate contact with cardiac structures. Once these markers indicate the tip is not in contact, the reading can be zeroed. Refer to the user manual for the CARTO™ 3 System for instructions on how to zero the contact force reading.
15. Zero the contact force reading when moving the catheter from one chamber of the heart to another or upon reinsertion.
16. Verify that the “QDOT MICRO” option is selected on the RF generator. When this option is chosen, the RF generator defaults to the safety parameters established for the QDOT MICRO™ Uni-Directional Navigation Catheter.

17. Table 1 below outlines the recommended ablation parameter settings when using the QDOT MICRO™ Uni-Directional Navigation Catheter for ablation in the atria:

**Table 1: Recommended Ablation Parameter Settings**

| Power Mode | QMODE* | | QMODE+ |
|---|---|---|---|
| Power (W) | 25-35 | 36-50 | 90 |
| Target Electrode Temperature (°C) | 50 | 50 | 60 |
| RF application time (s) | Up to 60 | Up to 60 | 4 |
| Nominal Irrigation flow rate (ml/min)** | 4*** | 15*** | 8 |

* RF applications on the left atrial posterior wall using QMODE should not exceed 35 W in power and 30 sec in duration.

** A minimum flow rate of 2 mL/min during mapping is recommended.

*** The irrigation flow rate is set by the generator and automatically adjusted between 4ml/min or 15ml/min to reach and maintain the set maximum power within the target electrode temperature.

- For the treatment typical atrial flutter, the QMODE is recommended.
- For the treatment of paroxysmal atrial fibrillation, the QMODE+ is recommended as the primary ablation mode for creating pulmonary vein isolation lesions and the QMODE is recommended for applications outside the PV ostia and for touch-up ablations.
- The QMODE power setting allows a maximum power up to 50 W, and the clinical operator may select any combination of power and RF application time, guided by the clinical judgment and expertise of the clinical operator as well as the anatomical area of interest.
- The QMODE+ power setting allows a maximum power up to 90 W, with a maximum RF application time up to 4 seconds. Use caution when overlapping RF ablation points, particularly on the posterior wall. Maintain appropriate contact force within the recommended range. This combination of power and RF application time is optimized for atrial ablation and may be used independently or in conjunction with the QMODE power setting.
- For ablations with any power setting, the clinical operator should monitor commonly used ablation effectiveness parameters like electrogram amplitude reduction and/or impedance drop.

Contact Force (CF) ranges during ablation:

The QFFICIENCY IDE study recommended CF settings to operators for use with the study catheter in both QMODE and QMODE+ as follows:

- CF Working Range: 5-30g

During the study, the overall average CF recorded during a study ablation procedure for all 166 subjects in the Per-Protocol Analyiss set was 15.4 ± 5.2 grams.

18. Do not use this catheter without irrigation flow. Do not alter the irrigation flow rate.
19. Monitor the catheter tip temperature response throughout the procedure to ensure adequate irrigation. If temperature increases very rapidly during RF application, power delivery should be interrupted. The irrigation system must be rechecked prior to restarting RF application. Note: The displayed temperature represents the temperature of the electrode only, not the temperature of the tissue.
20. In the event of a generator cutoff (impedance or temperature), the catheter must be withdrawn and the tip electrode inspected for coagulum before RF energy is reapplied. To remove any coagulum, if present, a sterile gauze pad dampened with sterile saline may be used to gently wipe the tip section clean. Do not scrub or twist the tip electrode as damage to the tip electrode bond may occur and loosen the tip electrode, or damage may also occur to the contact force sensor and affect measurement accuracy. Prior to reinsertion, flush the tip to ensure that the irrigation holes are not plugged.

If irrigation hole occlusion occurs:

a. Fill a 1-2 ml syringe with sterile saline and attach it to the stopcock on the end of the tubing set.
b. Inject the saline from the syringe into the catheter. A uniform flow of fluid should be visible from the tip of the catheter.
c. Repeat steps a and b, if necessary, until the holes are cleared.
d. Flush the catheter and tubing per standard technique to ensure purging of trapped air bubbles and to verify that the irrigation holes are patent.
e. The catheter can now be introduced into the patient.
f. Zero the catheter following reinsertion into the patient.

**WARNING: Do not continue use of the catheter if it is still occluded or if it is not functioning properly.**

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Revised: 2023-01

# QDOT MICRO™ Bi-Directional Navigation Catheter

## INSTRUCTIONS FOR USE

**Symbol Definitions**
Following definitions are for reference only. Please refer to the product label for applicable usage.

STERILE EO
Sterilized Using Ethylene Oxide


Do Not Re-Use


Caution


Consult Instructions for Use


Do not use if package is damaged.


Do not use if package is opened.


Keep Away from Sunlight


Keep Dry


Use-By Date

LOT
Batch Code

REF
Catalog Number


Contents: 1


Manufacturer


Date of Manufacture


Pin Connector

ELECTRODES EA
Electrodes

SPACING mm
Spacing


Temperature Limit

℞ only
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

x
Curve Type. Refer to label for colored circle containing applicable curve type.

NAV
Navigational Catheter

C3
Compatible with CARTO™ 3 EP Navigation System

# QDOT MICRO™ Bi-Directional Navigation Catheter

**Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.**

- STERILE. Sterilized using ethylene oxide.
- For single use only.
- Do not resterilize.
- Do not use if the package is open or damaged.

## DEVICE DESCRIPTION

The Biosense Webster QDOT MICRO™ Bi-Directional Catheter is a steerable multi-electrode luminal catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart and to transmit radiofrequency (RF) energy to the catheter tip electrode for ablation purposes. The catheter shaft measures 7.5 F with 8 F ring electrodes. For ablation, the catheter is used in conjunction with a compatible RF generator and a dispersive pad (indifferent electrode). The catheter has force-sensing technology that provides a real-time measurement of contact force between the catheter tip and the heart wall.

The catheter has a high-torque shaft with a bi-directional deflectable tip section containing an array of electrodes which includes a 3.5 mm tip dome. All of the electrodes may be used for recording and stimulation purposes. The tip electrode serves to deliver RF energy from the generator to the desired ablation site. The tip electrode and ring electrodes are made from noble metals. The catheter incorporates six thermocouple temperature sensors and three ECG electrodes that are embedded in the 3.5 mm tip electrode. A Rocker Lever is used to deflect the tip. The high-torque shaft also allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site. Additionally, a variety of curve types are available in symmetric or asymmetric combinations, providing two 180° opposed, single-planed curves. Five curve configurations designated “DD”, “FF”, “JJ”, “DF”, and “FJ” are available.

At the proximal end of the catheter, a saline input port with a standard Luer fitting terminates from the open lumen. This saline port serves to permit the injection of normal saline to irrigate the tip electrode. During ablation, heparinized normal saline is passed through the internal lumen of the catheter and through the tip electrode, to irrigate and cool the ablation site as well as the electrode tip. A compatible irrigation pump is used to control the saline irrigation. The catheter interfaces with standard recording equipment and a compatible RF generator via accessory extension cables with the appropriate connectors.

This catheter features a location sensor embedded in the tip section that transmits location and contact force information to the CARTO™ 3 Navigation System. An appropriate reference device is required for location reference position purposes. For information on using the catheter in mapping procedures and for information on appropriate reference devices, refer to the user manual for the CARTO™ 3 Navigation System. For further description of the operation of the irrigation pump, the generator, and the CARTO™ 3 Navigation System, refer to the applicable instructions for use.

## INDICATIONS FOR USE

The Biosense Webster QDOT MICRO™ Bi-Directional Navigation Catheter and related accessory devices are indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a compatible radiofrequency generator, for the treatment of:

- Type I atrial flutter in patients age 18 or older.
- Drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with compatible three-dimensional electroanatomic mapping systems.

The Biosense Webster QDOT MICRO™ Bi-Directional Navigation Catheter provides a real-time measurement of contact force between the catheter tip and heart wall, as well as location information when used with CARTO™ 3 Navigation System.

## CONTRAINDICATIONS

Do not use this catheter:

1. If the patient has had a ventriculotomy or atriotomy within the preceding twelve weeks because the recent surgery may increase the risk of perforation.
2. In patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolus.
3. In patients with prosthetic valves as the catheter may damage the prosthesis.
4. In the coronary arterial vasculature due to risk of damage to the coronary arterial vasculature.
5. In patients with an active systemic infection because this may increase the risk of cardiac infection.
6. Via the transseptal approach in a patient with an interatrial baffle or patch because the opening could persist and produce an iatrogenic atrial shunt.
7. Via the retrograde trans-aortic approach in patients who have had aortic valve replacement.
8. With a long sheath or short introducer < 8.5 F in order to avoid damage to the catheter shaft.

## WARNINGS AND PRECAUTIONS

1. Do not use excessive force to advance or withdraw the catheter when resistance is encountered during catheter manipulation through the sheath.
2. Do not manually pre-shape the distal shaft of the catheter by applying external forces intended to bend or affect the intended shape or curve of the catheter.
3. Prior to use, the catheter must be warmed up as specified in the Directions for Use section of this document. If the catheter has not reached a steady state condition, there is potential for a zero-offset drift to occur which could result in an inaccurate contact force reading.
4. Always zero the contact force reading following insertion into the patient or when moving the catheter from one chamber of the heart to another. Ensure the catheter is not in contact with heart tissue prior to zeroing. Refer to the user manual for your CARTO™ 3 System for instructions on how to zero the contact force reading.
5. The contact force reading might become inaccurate if the contact force sensor (located between the first and second ring electrode) comes into close proximity with a ferrous material, such as the braided shaft of another catheter. If extreme fluctuations in force are observed, ensure the catheter's contact force sensor is not in close proximity with another catheter's shaft, check zero on the catheter and, if necessary, remove and inspect the catheter. The contact force reading is for information only and is not intended to replace standard handling precautions.
6. To ensure proper operation of the contact force sensor, the tip electrode and the two distal ring electrodes must protrude from the distal tip of the guiding sheath.
7. When applying high lateral force during mapping and RF application, the user should monitor the contact force dashboard and vector display on the CARTO™ 3 System screen to ensure that contact force measurements remain within the accurate range. Refer to the Error Messages and Alerts section of the CARTO™ 3 System user manual for system-related alert messages and indications related to inaccurate force readings.
8. Do not use the temperature sensor to monitor tissue temperature. The temperature sensor located within the tip section of the catheter does not reflect either electrode-tissue interface or tissue temperature due to the cooling effects of the saline irrigation of the electrode. The temperature displayed on the generator is the temperature of the hottest of the six thermocouples in the electrode, not tissue temperature. Monitoring the temperature from the electrode during the application of RF energy ensures that the irrigation flow rate is being maintained.
9. At higher contact force settings, rapid power increases during ablation may result in steam pops, which increase the risk of perforation.
10. This catheter may damage the mechanical or prosthetic valve of a patient if the catheter is accidentally advanced through the valve.
11. The safety of discontinuing anticoagulation therapy following catheter ablation of atrial fibrillation has not been established. Anticoagulation therapy in such patients should be administered in accordance with the AHA/ACC/HRS 2014 Guideline for the Management of Patients With Atrial Fibrillation.

12. The safety and effectiveness of radiofrequency ablation for the treatment of atrial fibrillation in patients with significant left ventricular dysfunction, advanced heart failure, substantial left atrial enlargement, and structural heart disease have not been established.
13. In accordance with your hospital's protocol, monitor the patient's fluid balance throughout the procedure to avoid fluid volume overload. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible. Prior to the procedure, always identify the patient's risk of volume overload.
14. Implantable pacemakers and implantable cardioverter/defibrillator (ICDs) may be adversely affected by RF energy. It is important to have temporary external sources of pacing and defibrillation available during ablation and to temporarily reprogram the pacing system to minimum output or OFF mode to minimize the risk of inappropriate pacing. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent leads; program the ICD to the OFF mode during the ablation procedure; and, perform complete implantable device analysis on all patients after ablation.
15. Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Patients who experience inadvertent complete AV block as a result of RF ablation may also require permanent pacing.
16. During the trans-aortic approach, adequate visualization is necessary to avoid placement of the catheter in the coronary vasculature. Intracoronary placement of the ablation catheter, RF energy application, or both have been associated with myocardial infarction.
17. To prevent stenosis of the pulmonary veins, do not place the catheter in the pulmonary veins during the application of RF energy.
18. When ablating near adjacent anatomical structures, take precautions to minimize collateral damage to the adjacent structures.
19. When ablating near the phrenic nerve, take precautions to avoid injuring the phrenic nerve, including appropriately reducing RF power, pacing to identify the proximity of ablation electrode(s) to the nerve and/or fluoroscopic evaluation of the diaphragm post ablation.
20. When ablating near the esophagus (along the posterior wall of the left atrium), take precautions to avoid injuring the esophagus. These may include beginning the ablation with reduced RF power, reducing contact force, reducing application time, increasing the time interval between ablations, moving to new location if temperature rise observed, esophageal visualization, and/or intraluminal esophageal temperature monitoring.
21. Minimize or eliminate X-ray exposure during the procedure. Catheter ablation procedures using fluoroscopic imaging may present the potential for significant X-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the X-ray beam intensity and duration of fluoroscopic imaging. Catheter ablation, when using fluoroscopic imaging, should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must therefore be given for the use of the device in pregnant women.
22. Do not expose the catheter to organic solvents such as alcohol.
23. Do not autoclave the catheter.
24. Do not immerse the proximal handle or cable connector in fluids. Electrical performance could be affected.
25. Do not scrub or twist the distal tip electrode during cleaning.
26. Inspect the saline within the irrigation tubing for air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause emboli.
27. Purge the catheter and irrigation tubing with heparinized normal saline prior to insertion of the catheter inside the patient body.
28. Electrophysiology catheters and systems are intended for use only in X-ray shielded rooms due to electromagnetic compatibility requirements and other hospital safety guidelines.
29. Do not attempt to operate the QDOT MICRO™ Bi-Directional Catheter or the generator prior to completely reading and understanding the applicable instructions for use.

30. Cardiac ablation procedures should be performed by appropriately trained personnel in a fully equipped electrophysiology laboratory. Appropriate clinical instruction in the use of the QDOT MICRO™ Bi-Directional Catheter should also be completed.
31. The long-term risks of protracted fluoroscopy and creation of RF induced lesions have not been established. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
32. To prevent thromboembolism, intravenous heparin (target ACT of $\geq$ 350 s) should be administered prior to or immediately following transseptal puncture during AF ablation procedures. The 2017 HRS/EHRA/ECAS/AOHRS/SOLAECCE expert consensus statement on catheter and surgical ablation of atrial fibrillation recommends systemic anticoagulation with warfarin or a direct thrombin or factor Xa inhibitor for at least 2 months following an AF ablation procedure (Calkins H, Hindricks G, Cappato R et al. 2017 HRS/EHRA/ECAS/AOHRS/SOLAECCE Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation. J Interv Card Electrophysiol. 2017 50:1-55).
33. When using the QDOT MICRO™ Bi-Directional Catheter with conventional systems (such as fluoroscopy or ultrasound imaging), or with the CARTO™ 3 Navigation System, careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under direct imaging guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. The firmness of the braided tip dictates that care must be taken to prevent perforation of the heart. The contact force reading is for information only and is not intended to replace standard handling precautions.
34. Always place the Rocker Lever in the neutral position to straighten the catheter tip before insertion or withdrawal of the catheter.
35. Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter.
36. When RF energy is interrupted for either a temperature or an impedance rise (the set limit is exceeded), the catheter should be removed, and the tip should be inspected for char/coagulum that may be present on the tip. If present, do not continue the procedure with the same catheter and replace the catheter. If no char/coagulum is present, flush the tip to ensure the irrigation holes are not plugged prior to reinsertion of the catheter inside the patient body.
37. Apparent low power output, high impedance reading, or failure of the equipment to function correctly at normal settings may indicate faulty application of the indifferent electrode(s) or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication of the indifferent electrode or other electrical leads.
38. Read and follow the indifferent electrode manufacturer's instructions for use. The use of indifferent electrodes that meet or exceed ANSI/AAMI requirements (AAMI IEC 60601-2-2), is recommended.
39. The QDOT MICRO™ Bi-Directional Catheter is intended for use with a compatible RF generator, compatible irrigation pump, CARTO™ 3 Navigation System, Biosense Webster cables, and other appropriate interface cables and connectors. Use of a compatible irrigation pump is recommended to assure proper irrigation flow rate.
40. Care should be taken when ablating near structures such as the sino-atrial and atrioventricular nodes.
41. The sterile packaging and catheter should be inspected prior to use. Do not use if the packaging or catheter appears damaged.
42. The catheter is sterilized with ethylene oxide gas and should be used by the "Use By" date on the device package. Do not use the catheter if it is past the "Use By" date.
43. The QDOT MICRO™ Bi-Directional Catheter is intended for single patient use only.
44. Do not resterilize and reuse.
45. Do not use near MRI equipment since movement or heating of the catheter may occur and the image on the display may become distorted.
46. Use both direct imaging guidance (such as fluoroscopy or ultrasound) and electrogram data to monitor catheter advancement and reduce risk of tissue injury.
47. The QDOT MICRO™ Bi-Directional Catheter used in conjunction with a compatible RF generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and indifferent electrode, particularly when operating the catheter. During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces.

48. The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical suite.
49. Electromagnetic interference (EMI) produced by the QDOT MICRO™ Bi-Directional Catheter, when used in conjunction with a compatible RF generator during normal operation, may adversely affect the performance of other equipment.
50. Electrodes and probes used for monitoring and stimulating devices can provide paths for high frequency current. The risk of burns can be reduced but not eliminated by placing the electrodes and probes as far away as possible from the ablation site and the indifferent electrode. Protective impedance may reduce the risk of burns, and permit continuous monitoring of the electrocardiogram during energy delivery.
51. If the generator does not display temperature, verify that the cables from the catheter to the CARTO™ System Patient Interface Unit (PIU) and the cable from the CARTO™ System Patient Interface Unit (PIU) to the generator are properly connected. If temperature still is not displayed, there may be a malfunction in the temperature sensing system that must be corrected prior to applying RF power.
52. The temperature measurement accuracy of the QDOT MICRO™ Bi-Directional Catheter, as with any temperature measurement electrophysiology catheter, is determined by the temperature accuracy of all of the connected devices. Please consult the appropriate user manuals for the connected devices for the temperature accuracy specification.
53. Before use, verify irrigation ports are patent by infusing heparinized normal saline through the catheter and tubing.
54. Regularly inspect and test reusable cables and accessories.

## ADVERSE EVENTS

**NOTE: The adverse events in the following summary were observed in clinical studies involving only the use of the QDOT Micro™ Catheter.**

**Clinical trial for the QDOT Micro™ Catheter – Pivotal Study (Q-FFICIENCY)**
Of the 177 subjects in the Safety Analysis Set, 7 primary adverse events (AEs) were reported in 6 subjects. See the “Summary of Clinical Studies Conducted for the QDOT Micro™ Catheter” section below for a complete description of the AEs encountered during the study.

## SUMMARY OF CLINICAL STUDIES CONDUCTED FOR THE QDOT MICRO™ CATHETER

The following is a summary of the pivotal study (Q-FFICIENCY) performed under IDE for the QDOT Micro™ Catheter, using model numbers D-1394-XX-SI and D-1395-XX-SI. Data from this clinical study formed the basis for the US FDA PMA approval decision.

All patients underwent informed consent per the study protocol, and in compliance with the Code of Federal Regulations, 21 §50. The protocol and informed consent materials were reviewed and approved by the appropriate IRB prior to subject enrollment, and in compliance with the Code of Federal Regulations, 21 §56. Per the requirements of 21 CFR §812.20(b)(5), all participating investigators signed the Clinical Study Agreement prior to enrollment at their center, which included financial disclosure forms, current curricula vitae for the investigator and co-investigators, and written IRB approval for the investigational study. The clinical study was monitored in a manner consistent with 21CFR, Part 812, Subpart C, *Responsibilities of Sponsor.* Monitoring visits included, but were not limited to, verification of all study logs, verification that informed consent was being obtained in accordance with requirements described in the study protocol for all subjects participating in the study, verification of completeness of the Regulatory Binder, data source verification with the eCRFs, and identification and action to resolve any issues or problems with the study.

**A. Objective**
The primary objective of this trial was to demonstrate the safety and effectiveness of the QDOT MICRO™ catheter when used with the nMARQ™ RF generator in the treatment of drug refractory symptomatic paroxysmal atrial fibrillation (PAF) during standard electrophysiology mapping and RF ablation procedures.

**B. Study Design**

The study was a prospective, single arm, unblinded, multicenter, pivotal clinical investigation conducted at 25 investigational sites in the US.

The study planned to enroll up to 185 subjects who are candidates for catheter ablation. Bayesian adaptive design was used to assess early success at one interim analysis performed 6 months after enrollment was completed and when 30% of subjects in the study completed 12 months of follow-up.

A CT/MRA imaging sub-study was integrated in the pivotal study. The first 40 consecutively enrolled subjects were included in the sub-study and underwent a 3-month CT/MRA in addition to the baseline CT/MRA to assess incidence of PV stenosis.

B.1 - Study Objectives and Endpoints:

The objectives and endpoints for this study are presented in Table 1. Failure modes for the primary effectiveness endpoint are listed in Table 2.

**Table 1 – Objectives and Endpoints for Q-FFICIENCY Study**

| Objectives | Endpoints |
|---|---|
| **Primary** | |
| To demonstrate the safety and 12-month effectiveness of the QDOT MICRO™ catheter when used with the nMARQ™ RF generator for pulmonary vein isolation (PVI) in the treatment of subjects with drug refractory symptomatic paroxysmal atrial fibrillation (PAF). | • Primary safety endpoint: Incidence of any primary adverse event occurring within 7 days of the AF ablation procedure (initial or repeat procedure) using the QDOT MICRO™ catheter, except atrio-esophageal fistula and PV stenosis, which may also be considered as primary adverse events if occurring greater than 7 days and up to 90 days post the ablation procedure. Primary adverse events included the following: Death, myocardial infarction, PV stenosis, phrenic nerve injury/diaphragmatic paralysis, atrio-esophageal fistula, TIA, stroke/CVA, thromboembolism, pericarditis, cardiac tamponade/perforation, vagal nerve injury, major vascular access complications/bleeding, pulmonary edema (respiratory insufficiency), and heart block.<br>• Primary effectiveness endpoint: Freedom from documented atrial fibrillation (AF), atrial tachycardia (AT) or atrial flutter (AFL) (hereinafter collectively referred to as “atrial tachyarrhythmias") recurrence during the evaluation period (Day 91 through Day 365) and freedom from the following failure modes (defined in Table 2):<br>o Acute procedure failure<br>o Repeat ablation failure<br>o Antiarrhythmic drug failure |

| Objectives | Endpoints |
|---|---|
| **Secondary** | |
| To evaluate the incidence of (serious) adverse events during and after procedure up to 3 months following procedure | • Incidence of Unanticipated Adverse Device Effects (UADEs)<br>• Incidence of Serious Adverse Events (SAEs) within 7 days (early onset), > 7 to 30 days (peri-procedural) and > 30 days (late onset) of initial ablation<br>• Incidence of bleeding complication (ISTH definitions): a) major, b) clinically relevant non-major and c) minor bleeding |
| To evaluate Acute Procedural Success defined as confirmation of entrance block in all PVs | • Acute procedural success: Percent of subjects with electrical isolation of PVs (entrance block) at the end of the procedure<br>o The percent of subjects with electrical isolation of PVs (entrance block) using QMODE+ as only ablation strategy<br>• Percent of subjects with electrical isolation of PVs (entrance block) after first encirclement (evaluated prior to the 20-minute waiting period and adenosine/isoproterenol challenge)<br>• Percent of subjects with electrical isolation of all PVs (entrance block) after first encirclement without acute reconnection, after waiting period and adenosine/isoproterenol challenge<br>• Percent of subjects and % of PVs with touch-up (i.e. touch-up is used to remove ablation of acute reconnection) among all targeted veins and touch-up location<br>• Anatomical location of acute PV reconnection after first encirclement |
| To evaluate repeat ablation procedures during the 12-month period post-procedure | • Incidence (%) of repeat ablation procedures<br>• Percent PVs re-isolated among all the targeted PVs at repeat procedure<br>• Percent repeat ablation procedures requiring new linear lesions and/or identifying new foci outside of initially isolated area among the repeat ablation procedures |
| To evaluate the 12-month Single Procedure Success | • 12-month single procedure success: Freedom from documented AF/AFL/AT recurrence (episodes ≥ 30 secs) during the Effectiveness Evaluation Period after a single ablation procedure and off anti-arrhythmia drugs (AADs) during the effectiveness evaluation period |

**Table 2 – Failure Modes for Primary Effectiveness Endpoint**

| Failure Mode | Criteria |
|---|---|
| Acute procedural | • Failure to confirm entrance block in all pulmonary veins post-procedure.<br>• Use of a non-study catheter to treat left atrial ablation targets and cavo-tricuspid isthmus. |
| Repeat ablation | • > 2 repeat ablation procedures with the study catheter during the 3-Month blanking period (Day 0-90) after the index ablation procedure.<br>• Use of a non-study catheter to treat study arrhythmia ablation targets during the blanking period.<br>• Any repeat ablation procedure during the Evaluation Period. |
| Antiarrhythmic drug | • Taking a new Class I or III AAD for AF or a previously failed Class I or III AAD at a greater than the highest ineffective historical dose for AF during the evaluation period. |

B.2 - Safety and Effectiveness Performance Goals

B.2.1 - Safety Performance Goal

The study was designed to compare the primary safety endpoint to a pre-determined safety performance goal of 14%. Data from recent PAF ablation studies for devices similar to the device in the current study were reviewed as a first step to deriving the performance goal for the primary safety endpoint. A meta-analysis approach was taken to estimate the average composite endpoint rate. Based on the meta-analysis, the upper bound of the 95% confidence interval was estimated to be equal to 9%. The pre-determined performance goal of 14% would reflect an approximately 50% increase in risk from the upper bound of the 95% CI.

B.2.2 - Effectiveness Performance Goal

The study was designed to compare the primary effectiveness endpoint to a pre-determined performance goal of 50%, which is indicated as the minimum acceptable success rate at 12 months for a paroxysmal AF population in the 2017 HRS/EHRA/ECAS/APHRS/ SOLAECE Expert Consensus Statement on Catheter and Surgical Ablation of AF (Calkins, et al., 2017).

B.3 - Subject Accountability:

**Table 3 – Subject Accountability and Disposition**

| Subject Enrollment | n |
|---|---|
| Enrolled Subjects | 191 |
| Excluded Subjects | 14 |
| Study Catheter Inserted | 177 |
| Discontinued Subjects | 2 |
| RF Energy Delivered with Study Catheter | 175 |
| Death | 1 |
| Withdrawn | 7 |
| Early Termination Subjects | 0 |
| Lost to Follow Up Subjects | 5 |
| Completed Subjects | 162 |

Among the 191 enrolled subjects, 14 had no insertion of the study device and were excluded from the analysis sets for the following reasons:

- System connectivity related device deficiencies (n = 4)

- Not meeting study entrance criteria (n = 9)
- Occurrence of an adverse event (tamponade) before insertion of the study device (n = 1)

Two (2) subjects had the study catheter inserted but no RF applications were delivered due to system connectivity issues.

A total of 175 subjects received RF ablation using the study device. Among those, seven (7) subjects (4.0%) withdrew their consent and discontinued their study participation during follow-up from 48 to 384 days post ablation; five (5) subjects (2.9%) were lost to follow up between 104 days and 266 days post procedure; one (1) subject (0.6%) expired 7 months post procedure; and 162 subjects (92.6%) completed the 12-month follow-up visit.

B.3.1 - Subject Disposition

The following definitions were used to classify subjects:

**Table 4 – Subject Classifications**

| Disposition | Definition |
|---|---|
| Enrolled Subjects | Subjects who signed the informed consent. |
| Excluded Subjects | Subjects who were enrolled but never underwent insertion of the study catheter. |
| Discontinued Subjects | Subjects who had the investigational catheter inserted but did not undergo ablation (i.e., no RF energy was delivered via the study device). These discontinued subjects were followed up for 3 months. |
| Lost to Follow-up Subjects | Subjects who were enrolled, but contact was lost after the most recent follow-up visits (despite 3 documented attempts to contact the subject). |
| Withdrawn / Early Termination Subjects | Subjects who withdrew consent for study participation or were withdrawn by the investigator or were terminated from the study prior to completion of all follow-up visits. |
| Completed Subjects | Enrolled subjects who completed the 12-month follow-up visit and were not excluded, discontinued, withdrawn, early terminated, expired, or lost to follow-up from the study before the final study visit. |

B.3.2 - Analysis Sets

**Safety Analysis Set:** The Safety analysis set included all enrolled subjects who had the investigational device inserted, regardless of RF energy delivery.

**Modified Intent-To-Treat (mITT) Analysis Set:** The mITT analysis set consisted of all enrolled subjects who met all eligibility criteria and had the investigational device inserted.

**Per-Protocol (PP) Analysis Set:** The PP analysis set included subjects who satisfied the following criteria:

- Enrolled and met eligibility criteria
- Had undergone RF ablation
- Were treated with the study catheters and had been treated for the study related arrhythmia without major protocol deviations deemed to affect the scientific integrity of the study, included in the following list. No additional major protocol deviations beyond those below were identified that required exclusion of subjects from the Per Protocol analysis set
    - Missing all protocol-specified electronic effectiveness monitoring
    - Esophageal monitoring was not done per protocol and risk was not mitigated
    - The required waiting period of 20 minutes was not followed before pacing procedures and/or infusion of cardiac medications to induce AF/reconnection was not performed before the entrance block confirmation.

**Treatment Received Analysis Set:** The Treatment Received analysis set included all enrolled subjects who received RF ablation using the study catheter. This analysis set was created post-hoc because it was deemed relevant by the FDA.

**CT/MRA Analysis Set:** The CT/MRA set consisted of the first 40 subjects who are consecutively enrolled in the main arm of the study with 3-month CT/MRA assessment. The subject must have readable outcomes at baseline and 3 months.

## C. Results

C.1 - Subject Demographics:

**Table 5 – Subject Demographics (Enrolled Subjects, N=191)**

| Variables | All Subjects (N=191) | Safety Analysis Set (N=177) | mITT Analysis Set (N=167) | Per-Protocol Analysis Set (N=166) |
|---|---|---|---|---|
| Age (years) [1] | | | | |
| n | 191 | 177 | 167 | 166 |
| Mean | 63.5 | 63.3 | 63.1 | 63.2 |
| SD | 10.69 | 10.88 | 11.00 | 11.03 |
| Min/Max | 24 / 83 | 24 / 83 | 24 / 83 | 24 / 83 |
| Sex, n/N (%) | | | | |
| Male | 116 / 191 (60.7) | 106 / 177 (59.9) | 101 / 167 (60.5) | 101 / 166 (60.8) |
| Female | 75 / 191 (39.3) | 71 / 177 (40.1) | 66 / 167 (39.5) | 65 / 166 (39.2) |
| Race n (%) | | | | |
| White, n/N (%) | 166 / 191 (86.9) | 157 / 177 (88.7) | 149 / 167 (89.2) | 148 / 166 (89.2) |
| Black or African American | 7 / 191 (3.7) | 6 / 177 (3.4) | 6 / 167 (3.6) | 6 / 166 (3.6) |
| Asian | 1 / 191 (0.5) | 1 / 177 (0.6) | 1 / 167 (0.6) | 1 / 166 (0.6) |
| Race not reported | 17 / 191 (8.9) | 13 / 177 (7.3) | 11 / 167 (6.6) | 11 / 166 (6.6) |
| Ethnicity, n/N (%) | | | | |
| Not Hispanic or Latino | 164 / 191 (85.9) | 154 / 177 (87.0) | 146 / 167 (87.4) | 145 / 166 (87.3) |
| Hispanic or Latino | 8 / 191 (4.2) | 6 / 177 (3.4) | 6 / 167 (3.6) | 6 / 166 (3.6) |
| Not reported | 19 / 191 (9.9) | 17 / 177 (9.6) | 15 / 167 (9.0) | 15 / 166 (9.0) |

C.2 - Baseline Characteristics:

**Table 6 – Medical History (Enrolled Subjects, N=191)**

| Medical History | Enrolled Subjects (N=191) | Safety Analysis Set (N=177) | mITT Analysis Set (N=167) | Per-Protocol Analysis Set (N=166) |
|---|---|---|---|---|
| **Cardiovascular** | 156 / 191 (81.7) | 143 / 177 (80.8) | 135 / 167 (80.8) | 134 / 166 (80.7) |
| Congestive heart failure | 16 / 191 (8.4) | 10 / 177 (5.6) | 9 / 167 (5.4) | 9 / 166 (5.4) |

| Medical History | Enrolled Subjects (N=191) | Safety Analysis Set (N=177) | mITT Analysis Set (N=167) | Per-Protocol Analysis Set (N=166) |
|---|---|---|---|---|
| Coronary artery disease | 39 / 191 (20.4) | 36 / 177 (20.3) | 33 / 167 (19.8) | 33 / 166 (19.9) |
| Vascular disease | 25 / 191 (13.1) | 23 / 177 (13.0) | 22 / 167 (13.2) | 22 / 166 (13.3) |
| Myocardial infarction | 13 / 191 (6.8) | 12 / 177 (6.8) | 10 / 167 (6.0) | 10 / 166 (6.0) |
| Hypertension | 131 / 191 (68.6) | 122 / 177 (68.9) | 116 / 167 (69.5) | 115 / 166 (69.3) |
| Cardiomyopathy | 15 / 191 (7.9) | 11 / 177 (6.2) | 10 / 167 (6.0) | 10 / 166 (6.0) |
| Left ventricular hypertrophy | 1 / 191 (0.5) | 1 / 177 (0.6) | 1 / 167 (0.6) | 1 / 166 (0.6) |
| Significant valvular disease | 3 / 191 (1.6) | 1 / 177 (0.6) | 1 / 167 (0.6) | 1 / 166 (0.6) |
| **Thromboembolic Events** | 20 / 191 (10.5) | 18 / 177 (10.2) | 16 / 167 (9.6) | 16 / 166 (9.6) |
| Transient ischemic attack | 5 / 191 (2.6) | 4 / 177 (2.3) | 3 / 167 (1.8) | 3 / 166 (1.8) |
| Stroke | 6 / 191 (3.1) | 5 / 177 (2.8) | 5 / 167 (3.0) | 5 / 166 (3.0) |
| Pulmonary embolus | 2 / 191 (1.0) | 2 / 177 (1.1) | 2 / 167 (1.2) | 2 / 166 (1.2) |
| **Diabetes** | 37 / 191 (19.4) | 36 / 177 (20.3) | 33 / 167 (19.8) | 33 / 166 (19.9) |
| **Obstructive Sleep Apnea** | 50 / 191 (26.2) | 46 / 177 (26.0) | 44 / 167 (26.3) | 44 / 166 (26.5) |
| CPAP Use | 36 / 191 (18.8) | 34 / 177 (19.2) | 33 / 167 (19.8) | 33 / 166 (19.9) |
| **$CHA_2DS_2$-VASc score** | 2.4 ± 1.51 | 2.4 ± 1.53 | 2.4 ± 1.49 | 2.4 ± 1.50 |
| **AF History (months)** | 48.6 ± 73.63 | 49.6 ± 75.29 | 51.7 ± 76.92 | 51.9 ± 77.11 |
| **PAF Episodes Within 12 Months** | 24.9 ± 89.91 | 25.2 ± 92.80 | 26.0 ± 95.22 | 25.7 ± 95.38 |
| **AAD Failed- Class I&III** | 1.2 ± 0.50 | 1.2 ± 0.50 | 1.2 ± 0.52 | 1.2 ± 0.52 |
| **Arrhythmia other than Atrial Fibrillation** | 87 / 191 (45.5) | 81 / 177 (45.8) | 73 / 167 (43.7) | 73 / 166 (44.0) |
| Left/right Atrial Tachycardia (AT) | 8 / 191 (4.2) | 8 / 177 (4.5) | 7 / 167 (4.2) | 7 / 166 (4.2) |
| Supraventricular Tachycardia (SVT) | 22 / 191 (11.5) | 20 / 177 (11.3) | 14 / 167 (8.4) | 14 / 166 (8.4) |
| Atrial flutter (AFL) | 43 / 191 (22.5) | 41 / 177 (23.2) | 40 / 167 (24.0) | 40 / 166 (24.1) |
| AVNRT | 0 / 191 (0.0) | 0 / 177 (0.0) | 0 / 167 (0.0) | 0 / 166 (0.0) |
| Accessory pathway | 0 / 191 (0.0) | 0 / 177 (0.0) | 0 / 167 (0.0) | 0 / 166 (0.0) |
| Ventricular tachycardia | 2 / 191 (1.0) | 2 / 177 (1.1) | 2 / 167 (1.2) | 2 / 166 (1.2) |
| **LA Diameter (mm)** | 38.06 ± 6.042 | 37.95 ± 5.917 | 38.09 ± 5.974 | 38.16 ± 5.917 |
| **LVEF (%)** | 59.4 ± 7.31 | 59.6 ± 7.02 | 59.7 ± 6.98 | 59.7 ± 6.99 |

Values in table represent n/N (%) or mean ± SD, as appropriate.

C.3 - Index Ablation Procedure

**Ablation protocol**

A circumferential anatomical approach was used to isolate all PVs. Confirmation of entrance block in all PVs was required by the protocol with a 20-minute waiting period after the last PV encircling lesion, during isoproterenol infusion and/or after adenosine bolus.

The study ablation procedure used both QMODE and QMODE+ temperature control modes. The primary mode of ablation for PVI was QMODE+. QMODE was used for PVI once the investigator deemed

QMODE+ unable to complete PVI. QMODE was used primarily for RF application outside the PV ostia and for touch-up of the PVI, if necessary.

Table 7 and Table 8 present the ablation parameters for the QMODE+ mode and QMODE mode, respectively.

**Table 7 – QMODE+ RF and Flow Rate Settings during RF applications**

| Power (W) | Target Temp (ºC) | | Cut-off Temp (ºC) | | Nominal Irrigation Flow rate (mL) |
|---|---|---|---|---|---|
| | Range | Maximum allowed | Range | Maximum allowed | |
| 90† | 40-60 | 60 | 60-70 | 70 | 8 |

† RF applications at this setting were limited to 4 sec. It was recommended to use lower target temperature setting for the posterior wall RF applications.

**Table 8 – QMODE Ablation Parameters***

| Power (W) | Target Temp (ºC) | | Cut-off Temp (ºC) | | Nominal Irrigation Flow rate (mL) |
|---|---|---|---|---|---|
| | Range | Recommended | Range | Recommended | |
| 25-35 | 45-50 | 50 | 50-55 | 55 | 4 |
| 36-50 | 45-50 | 50 | 50-55 | 55 | 15 |

* The study protocol recommended a maximum duration of 60 sec for RF applications using QMODE in general. For RF applications on the left atrial posterior wall, a maximum power of 35 W and a maximum duration of 30 sec were recommended.

Linear ablation lines were only required to treat documented macro-re-entry atrial tachycardias (ATs) and limited to the following targets only:

- LA roof line;
- Mitral Valve (MV) isthmus line;
- LA floor line;
- Cavo tricuspid isthmus (CTI).

A right atrial CTI linear ablation was required in cases with documented typical atrial flutter either before or during the procedure.

Prophylactic ablation of empirical sites was not allowed.

Ablation of spontaneous non-PV triggers was required.

Complex fractionated atrial electrogram (CFAE) ablation was not recommended.

All linear lesions required confirmation of bidirectional conduction block by pacing and/or mapping maneuvers.

The recommended contact force working range was 5-30 grams for both QMODE and QMODE+ modes.

**Procedural Data**

Among the 166 subjects in the PP analysis set, 59 subjects underwent the entire index procedure using QMODE+ mode only and 107 subjects using both QMODE+ & QMODE modes. QMODE+ only was used for PVI in 91 subjects in the PP cohort. Of the 91 subjects, 32 subjects received ablations outside PVs as well using QMODE.

Table 9-11 present the procedural data of the index procedures.

**Table 9 – Summary of Power, Temperature and Impedance Data Per Procedure (Per-Protocol Analysis Set, N=166)**

| Description | QMODE+ Only n=59 | QMODE+ and QMODE n=107 |
|---|---|---|
| Average Power (W) | 84.333 ± 0.4099 | 75.893 ± 7.5338 |
| Average Temperature (°C) | 39.415 ± 2.5587 | 39.555 ± 2.6122 |
| Average Impedance Drop (ohms) | 9.59 ± 1.696 | 9.47 ± 2.434 |

Values in table represent mean ± SD.

**Table 10 – Summary of Ablation Procedure Parameters (Per-Protocol Analysis Set, N=166)**

| Variable | Per- Protocol Analysis Set, N=166 | QMODE+ Only, N=59 | QMODE + and QMODE Combined N=107 |
|---|---|---|---|
| **Total mapping time (min)** | | | |
| n | 166 | 59 | 107 |
| Mean ± SD | 10.49 ± 10.593 | 10.29 ± 7.575 | 10.61 ± 11.968 |
| **Total procedure time (min)** | | | |
| n | 166 | 59 | 107 |
| Mean ± SD | 144.26 ± 51.101 | 122.27 ± 28.463 | 156.38 ± 56.604 |
| **Total fluoroscopy duration (min)** | | | |
| n | 165 | 59 | 106 |
| Mean ± SD | 10.81 ± 10.600 | 8.65 ± 7.935 | 12.01 ± 11.690 |
| **Total time to achieve PVI (min)** | | | |
| n | 165 | 58 | 107 |
| Mean ± SD | 25.32 ± 33.948 | 16.38 ± 20.891 | 30.17 ± 38.483 |
| **Total RF application time for ablating PVs (min)** | | | |
| n | 165 | 58 | 107 |
| Mean ± SD | 11.66 ± 11.322 | 7.33 ± 5.273 | 14.01 ± 12.944 |
| **Fluid delivered via the study catheter (mL)** | | | |
| n | 154 | 52 | 102 |
| Mean ± SD | 546.5 ± 298.55 | 434.4 ± 190.79 | 603.7 ± 326.90 |
| **Fluid delivered via intravenous fluids (mL)** | | | |
| n | 159 | 56 | 103 |
| Mean ± SD | 861.2 ± 557.28 | 744.5 ± 472.39 | 924.7 ± 590.93 |

**Table 11 – Number of RF Applications, Average Duration of RF Application and Average Contact Force per Ablation Procedure (Per-Protocol Analysis Set, N=166)**

| Variable | QMODE+ Only n=59 | QMODE+ and QMODE Combined n=107 |
|---|---|---|
| **Number of RF Applications** | | |
| Mean ± SD | 100.5 ± 39.36 | 132.7 ± 41.80 |
| **Average Duration of RF Application (sec)*** | | |
| Mean ± SD | 3.870 ± 0.0393 | 7.384 ± 4.5099 |
| **Average Contact Force (g)** | | |
| Mean ± SD | 15.800 ± 5.3346 | 15.194 ± 5.1492 |

* Applications with RF energy >0 W and duration of RF application ≥1 sec were included for analysis.

**Ablation Targets**

Table 12 summarizes ablation targets. As required by the protocol, PVs were targeted in all index procedures. Among the PP analysis set, about 40% of the subjects received ablations beyond PVI.

**Table 12 – Ablation Sites Targeted (Per-Protocol Analysis Set, N=166)**

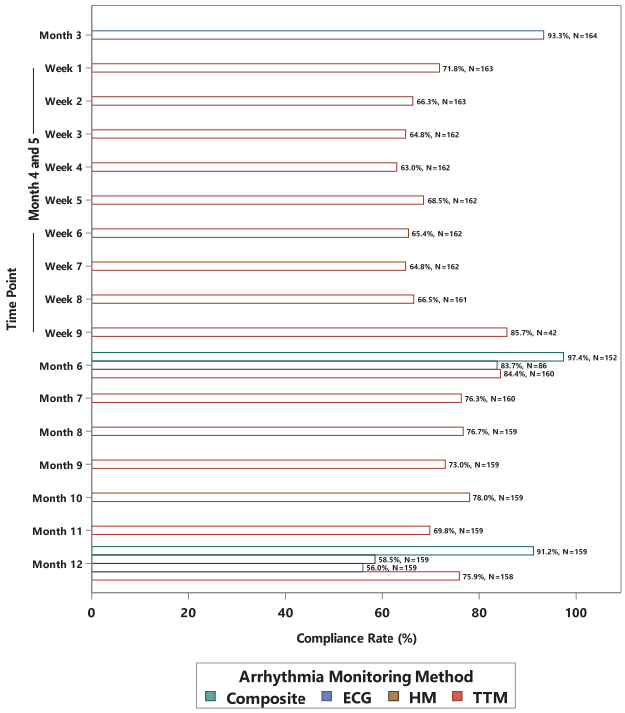
| Ablation Sites Targeted | Number of Subjects |
|---|---|
| **Total** | 166 |
| **PVI only** | 100 / 166 (60.2%) |
| **Non-PV** | 66 / 166 (39.8%) |
| Roof line | 16 / 66 (24.2%) |
| Cavo-tricuspid isthmus | 46 / 66 (69.7%) |
| Other linear lesion | 15 / 66 (22.7%) |
| Other AF foci | 16 / 66 (24.2%) |
| Other | 3 / 66 (4.5%) |

C.4 - Rhythm Monitoring Compliance

During the 9-month evaluation period, rhythm monitoring included symptomatic and scheduled asymptomatic TTM transmissions (weekly from Month 3 visit through Month 5 post ablation and monthly starting from Month 6 to Month 12), 12-lead ECG at 3 and 12 months and at 6 months if subject returned for an in-clinic visit, and 24-hour Holter at Month 12.

Figure 1 shows the TTM, 12-lead ECG, and Holter compliance rates at each evaluation time point in the Per-Protocol Analysis Set. The overall TTM and Holter compliance rates were 70.3% and 58.5%, respectively. The ECG compliance rate was 93.3%, 83.7%, and 56.0% at Month 3, 6, and 12, respectively. The composite compliance rate was 97.4% and 91.2% at Month 6 and Month 12, respectively, where at least two rhythm monitoring methods were required per protocol.

**Figure 1 – TTM/ECG/HM Compliance by Time Point (Per-Protocol Analysis Set, N=166)**




## C.5 - Safety Results

### C.5.1 - Primary Safety Endpoint

*Primary Analysis*

The primary safety endpoint for this study was defined as the incidence of early onset Primary AEs for subjects undergoing a study ablation procedure. Per study protocol, the primary safety analysis was based on primary safety event rate using the mITT analysis set (N=166) as the primary analysis population.

Table 13 displays a summary for the primary safety endpoint in subjects with non-missing outcomes in the mITT analysis set. The raw incidence was 3.6%. The posterior mean of PAE rate was 4.2%, with a 95% Bayesian credible interval (BCI) ranging from 1.7% to 7.7%. This is well below the performance goal of 14%. The posterior probability that the PAE rate less than the performance goal of 0.14 was close to 1.0000 (i.e., > 0.99995), which exceeded the early success threshold of 0.975. The study met the early success threshold for the primary safety endpoint. There were no changes to the primary safety endpoint data between the early success interim analysis and the final analysis.

**Table 13 – Summary of Primary Safety Endpoint Analysis (mITT Analysis Set, N=167)**

| | |
|---|---|
| Subjects with Primary Safety Events | 6 |
| Subjects without Primary Safety Events | 160 |
| Missing | 1 |
| Raw Incidence | 3.6% |
| Posterior Mean* | 4.2% |
| 95% BCI | (1.7%, 7.7%) |
| Posterior Probability* that rate < 0.14 | 1.0000 |
| Threshold to Pass | 0.9750 |
| Pass? | Yes |

* Using Beta (1,1) prior distribution

Table 14 presents the descriptive summaries by type of primary adverse events, which were adjudicated by CEC. The PAEs reported in this study were as follows: Three (3) major vascular access complication/bleeding events (reported in 3 subjects, 1.8%), two (2) cardiac tamponade/perforation events (2 subjects, 1.2%), and two (2) phrenic nerve injury/diaphragmatic paralysis events (1 subject, 0.6%). Both cardiac tamponade/perforation events required pericardiocentesis and one of them required blood transfusion; both were adjudicated as procedure related and possibly device related. The three (3) major vascular access complications were adjudicated as procedure related and included one femoral artery pseudoaneurysm requiring thrombin injection, one retroperitoneal bleed and one arteriovenous fistula. The events of phrenic nerve injury/diaphragmatic paralysis were adjudicated as both device and procedure related.

The subject adjudicated by CEC as phrenic nerve injury/diaphragmatic paralysis was re-evaluated at the 12-month visit to determine if the phrenic nerve injury is permanent and was deemed non-assessable by CEC. The sponsor has conservatively counted the adverse event as a PAE.

**Table 14 – Primary Safety Endpoint Outcome – Primary AEs (mITT Analysis Set, N=167)**

| Variable | Number of Subjects with Event | Number of Events | Event Rate n/N (%) [1] |
|---|---|---|---|
| **Primary Adverse Event** | 6 | 7 | 6 / 166 (3.6%) |
| **Type of Primary Adverse Event** | | | |
| Death (Device or procedure related) | 0 | 0 | 0 / 166 (0.0%) |
| Atrio-Esophageal Fistula | 0 | 0 | 0 / 166 (0.0%) |
| Cardiac Tamponade/Perforation | 2 | 2 | 2 / 166 (1.2%) |
| Myocardial Infarction | 0 | 0 | 0 / 166 (0.0%) |
| Stroke/Cardiovascular Accident (CVA) | 0 | 0 | 0 / 166 (0.0%) |
| Thromboembolism | 0 | 0 | 0 / 166 (0.0%) |
| Transient ischemic Attack (TIA) | 0 | 0 | 0 / 166 (0.0%) |
| Phrenic Nerve Injury / Diaphragmatic Paralysis | 1 | 2 | 1 / 166 (0.6%) |
| Heart Block | 0 | 0 | 0 / 166 (0.0%) |
| Pulmonary Vein Stenosis | 0 | 0 | 0 / 166 (0.0%) |
| Pulmonary Edema (Respiratory Insufficiency) | 0 | 0 | 0 / 166 (0.0%) |
| Vagal Nerve Injury | 0 | 0 | 0 / 166 (0.0%) |
| Pericarditis | 0 | 0 | 0 / 166 (0.0%) |
| Major Vascular Access Complication / Bleeding | 3 | 3* | 3 / 166 (1.8%) |

[1] One subject did not experience a PAE and exited the study prior to 3-month follow-up visit; subject was excluded from this analysis.

* Major vascular access complication/bleeding events included one retroperitoneal hemorrhage, one vascular access site hemorrhage and one pseudoaneurysm.

*Sensitivity Analysis*

The primary safety endpoint was also analyzed in the Safety Analysis set because it is considered by the FDA as a more clinically relevant analysis population for device safety evaluation. Of the 176 subjects in the Safety analysis set, 10 underwent the study ablation procedure and had the study catheter inserted but were identified post-procedure to not meet eligibility criteria for the study. These subjects were not included in the mITT analysis set but were included in the Safety analysis set. No PAEs were reported in these 10 subjects. One (1) subject withdrew from the study 48 days post the index procedure with no PAE, was considered missing and excluded from this analysis.

As summarized in Table 15, the rate of PAE was 3.4% (6/176) in the safety analysis set. The posterior mean of the PAE rate was 3.9%, with an 95% BCI ranging from 1.6% to 7.2%. With 10 more subjects in the analysis, the posterior probability of the PAE rate being less than 0.14 remain greater than 0.9999 which is well above the threshold of 0.975.

**Table 15 – Summary of Primary Safety Endpoint Analysis (Safety Analysis Set, N=177)**

| | |
|---|---|
| Subjects with Primary Safety Events | 6 |
| Subjects without Primary Safety Events | 170 |
| Missing | 1 |
| Raw Incidence | 3.4% |
| Posterior Mean* | 3.9% |
| 95% BCI* | (1.6%, 7.2%) |
| Posterior Probability* that rate < 0.14 | 1.0000 |
| Threshold to Pass | 0.9750 |

* Using Beta (1,1) prior distribution

C.5.2 - Incidence of UADEs

There were no UADEs reported in the study.

C.5.3 - Incidence of Early Onset, Peri-Procedural and Late Onset SAEs

Table 16 Summaries the incidence of early onset, peri-procedural and late onset SAEs in the Safety Analysis set.

**Table 16 – Serious Adverse Events by Timing of Onset (Safety Analysis Set, N=177)**

| Serious Adverse Events - by Timing of Onset [1] | Number of Events | Number of Subjects with Event | Event Rate [2] n/N (%) |
|---|---|---|---|
| **Total** | 55 | 34 | |
| 0 - 7 Days | 14 | 12 | 12 / 177 (6.8%) |
| 8 - 30 Days | 5 | 4 | 4 / 177 (2.3%) |
| > = 31 Days | 36 | 25 | 25 / 177 (14.1%) |

Note: This table summarizes all SAEs. Adjudication for seriousness is based on CEC for PAEs or site for non-PAEs.

[1] Including events on and after the day of procedure. Timing of AE based on onset in days post procedure (index or repeat).

[2] N denotes number of subjects with follow-up duration corresponding to each time interval.

Table 17 summarizes the SAEs (by causality and body system) occurring within 30 days of a study ablation procedure that were not classified as Primary AEs by protocol definition.

**Table 17 – Serious Non-Primary AEs Occurring within 30 Days Post Index/Repeat Ablation Procedure) by Causality and Body System (Safety Analysis Set, N=177)**

| Relationship to the Device/Procedure by Body System | Number of Subjects with Event | Number of Events [1] | Event Rate [2] |
|---|---|---|---|
| **Overall** | 11 | 13 | 11 / 177 (6.2%) |
| | | | |
| **Causal Relationship to Device** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |

| Relationship to the Device/Procedure by Body System | Number of Subjects with Event | Number of Events [1] | Event Rate [2] |
|---|---|---|---|
| **Probable Device Related** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |
| **Possible Device Related** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |
| **Unlikely Device Related** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |
| **Not Device Related** | 11 | 13 | 11 / 177 (6.2%) |
| Cardiac disorders | 7 | 8 | 7 / 177 (4.0%) |
| Atrial fibrillation | 3 | 3 | 3 / 177 (1.7%) |
| Atrial flutter | 2 | 2 | 2 / 177 (1.1%) |
| Congestive Cardiac failure | 1 | 1 | 1 / 177 (0.6%) |
| Cardiac tamponade | 1 | 1 | 1 / 177 (0.6%) |
| Pericardial effusion | 1 | 1 | 1 / 177 (0.6%) |
| General disorders and administration site conditions | 3 | 3 | 3 / 177 (1.7%) |
| Chest pain | 2 | 2 | 2 / 177 (1.1%) |
| Pyrexia | 1 | 1 | 1 / 177 (0.6%) |
| Respiratory, thoracic and mediastinal disorders | 1 | 1 | 1 / 177 (0.6%) |
| Pulmonary embolism | 1 | 1 | 1 / 177 (0.6%) |
| Vascular disorders | 1 | 1 | 1 / 177 (0.6%) |
| Arteriovenous fistula | 1 | 1 | 1 / 177 (0.6%) |
| | | | |
| **Causal Relationship to Procedure** | 1 | 1 | 1 / 177 (0.6%) |
| General disorders and administration site conditions | 1 | 1 | 1 / 177 (0.6%) |
| Chest pain | 1 | 1 | 1 / 177 (0.6%) |
| | | | |
| **Probable Procedure Related** | 3 | 5 | 3 / 177 (1.7%) |
| Cardiac disorders | 2 | 3 | 2 / 177 (1.1%) |
| Congestive Cardiac failure | 1 | 1 | 1 / 177 (0.6%) |
| Cardiac tamponade | 1 | 1 | 1 / 177 (0.6%) |
| Pericardial effusion | 1 | 1 | 1 / 177 (0.6%) |
| Respiratory, thoracic and mediastinal disorders | 1 | 1 | 1 / 177 (0.6%) |
| Pulmonary embolism | 1 | 1 | 1 / 177 (0.6%) |
| Vascular disorders | 1 | 1 | 1 / 177 (0.6%) |
| Arteriovenous fistula | 1 | 1 | 1 / 177 (0.6%) |
| | | | |
| **Possible Procedure Related** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |
| **Unlikely Procedure Related** | 0 | 0 | 0 / 177 (0.0%) |
| | | | |

| Relationship to the Device/Procedure by Body System | Number of Subjects with Event | Number of Events [1] | Event Rate [2] |
|---|---|---|---|
| **Not Procedure Related** | 7 | 7 | 7 / 177 (4.0%) |
| Cardiac disorders | 5 | 5 | 5 / 177 (2.8%) |
| Atrial fibrillation | 3 | 3 | 3 / 177 (1.7%) |
| Atrial flutter | 2 | 2 | 2 / 177 (1.1%) |
| General disorders and administration site conditions | 2 | 2 | 2 / 177 (1.1%) |
| Chest pain | 1 | 1 | 1 / 177 (0.6%) |
| Pyrexia | 1 | 1 | 1 / 177 (0.6%) |

[1] Timing of AE based on onset in days post the procedure (index or repeat).

[2] Event rate is the percentage of subjects with the event.

C.5.4 - Subject Death

There was one (1) death during the study. The subject was a 66-year-old male with history of PAF and multiple comorbidities (coronary artery disease, hypertension, non-ischemic cardiomyopathy, congestive heart failure, status post-biventricular pacer for cardiac resynchronization therapy). He underwent the study procedure without immediate complications. Five months following the ablation procedure, the subject suffered a witnessed cardiac arrest due to ventricular fibrillation and was resuscitated by immediate cardiopulmonary resuscitation and external defibrillations 10 minutes after the onset of ventricular fibrillation. He subsequently suffered from anoxic brain injury and pneumonia without clinical improvement after therapy. The subject expired about 7 months post ablation. The death was classified as not related to the procedure or the device by the investigator.

C.5.5 - CT/MRA Sub-Set Analysis

Table 18 presents the results of the CT/MRA subset analysis. A total of 40 subjects in the CT/MRA subset underwent the CT/MRA imaging of the PVs pre-procedure and 3 months post-procedure. No subjects showed moderate or severe pulmonary vein stenosis in the subset.

**Table 18 – PV Narrowing Post Ablation (CT/MRA Analysis Set, N=40)**

| Pulmonary Vein Stenosis | | Mild | | Moderate | Severe |
|---|---|---|---|---|---|
| | **Less than 0%** | **0-20%** | **20-50%** | **50-70%** | **> 70%** |
| Subject-Level Summary, n/N (%) | 1 / 40 (2.5%) | 15 / 40 (37.5%) | 24 / 40 (60.0%) | 0 / 40 (0.0%) | 0 / 40 (0.0%) |

C.6 - Effectiveness Results

C.6.1 - Primary Effectiveness Endpoint

*Primary Analysis*

Per study protocol, the primary effectiveness analysis was based on primary effectiveness success using the PP Analysis Set as the primary analysis population.

An early success interim analysis was performed as pre-specified in the protocol with a data extract obtained on June 22nd, 2020 and repeated after the endpoint was met with an additional data extract obtained on August 14th, 2020 to incorporate FDA feedback.

At the planned interim analysis, the posterior mean of event-free rate at Month 12 was 74.5%, with a 95% Bayesian credible interval (BCI) ranging from 66.6% to 81.5%. The posterior probability that the

event-free rate at Month 12 was greater than the performance goal of 50% was close to 1.0000 (i.e., 0.99995), which exceeded the pre-specified threshold of 0.9975. The primary effectiveness endpoint was therefore met at the early success interim analysis.

The analysis of the primary effectiveness endpoint on the August 14, 2020 data extract yielded similar results. These results have been updated with complete follow-up on the full cohort using a beta-binomial model with a non-informative prior. The final primary effectiveness rate is nearly identical to the interim estimate.

Table 19 presents the primary effectiveness analysis based on interim analysis and final analysis in the PP Analysis set.

**Table 19 – Summary of Primary Effectiveness Endpoint Analysis based on the Interim Analysis and Final Analysis (Per-Protocol Analysis Set, N=166)**

| | Jun-22, 2020 Data | Aug-14, 2020 Data | Final Data |
|---|---|---|---|
| | **Based on 3-piece exponential model** | **Based on 3-piece exponential model** | **Based on Beta-Binomial Model** |
| **Kaplan-Meier Estimate (39 weeks)** | 0.765 | 0.778 | 0.767 |
| **Posterior Mean** | 0.745 | 0.755 | 0.759 |
| **95% BCI** | (0.666, 0.815) | (0.684, 0.820) | (0.690, 0.823) |
| **Posterior Probability that $P_E$ > 0.50** | 1.0000 | 1.0000 | 1.0000 |
| **Threshold to Pass** | 0.9975 | 0.9975 | |
| **Pass** | Yes | Yes | |

The first failure reason for subjects in the Per-Protocol analysis set is presented in Table 20. Ten (10) subjects with missing effectiveness outcomes are excluded from the summary. Approximately seventy six percent (76.3%, 119/156) of the Per-Protocol population were free from documented atrial tachyarrhythmias and additional failure modes during their effectiveness evaluation period. Documented recurrence of atrial tachyarrhythmias (17.3%, 27/156) and repeat ablation failures (2.6%, 4/156) were the most common reasons for first failure.

**Table 20 – Primary Effectiveness Endpoint by Reason of The First Failure (Per-Protocol Analysis Set, N=166)**

| Variable | Number of Subjects with Event | Event Rate n/N (%) [1] |
|---|---|---|
| Success | 119 | 119/156 (76.3%) |
| First Failures [2] | 37 | 37/156 (23.7%) |
| Atrial Tachyarrhythmia Recurrence | 27 | 27/156 (17.3%) |
| AF | 25 | 25/156 (16.0%) |
| AFL | 2 | 2/156 (1.3%) |
| AT | 0 | 0/156 (0.0%) |
| Acute Procedural Failure | 3 | 3/156 (1.9%) |
| Acute Procedural Failure - Non-study Catheter | 3 | 3/156 (1.9%) |
| Acute Procedural Failure - Entrance Block | 0 | 0/156 (0.0%) |
| Repeat Ablation | 4 | 4/156 (2.6%) |
| AAD Failure | 3 | 3/156 (1.9%) |
| AAD Failure - New Drug | 3 | 3/156 (1.9%) |

| Variable | Number of Subjects with Event | Event Rate n/N (%) [1] |
|---|---|---|
| AAD Failure - High Dose | 0 | 0/156 (0.0%) |
| Missing | 10 | |

[1] N is the number of subjects with non-missing primary effectiveness endpoint.

[2] First failures: If a subject has at least 1 failure event, only the earliest failure event is considered and ed by its failure mode.

*Sensitivity Analysis*

Sensitivity to Analysis Sets

Table 21 presents the posterior means of event-free rate at Month 12 using the beta binomial model in the mITT, Safety and Treatment Received Analysis Sets based on the final full follow up data. The Treatment Received Analysis Set was included in the sensitivity analyses per FDA's feedback because it is considered by the FDA as the most clinically relevant analysis population for device effectiveness evaluation. The results suggested that the success rates in all three Analysis Sets met the effectiveness performance goal. Of note, of the two (2) discontinued subjects who had the study catheter inserted but received no RF ablation from the device, one was not included in the mITT Analysis Set due to study eligibility criteria violation, both were included in the Safety Analysis Set and neither was included in the Treatment Received Analysis Set. Both discontinued subjects were classified as primary effectiveness failures due to use of a non-study catheter for PVI in the respective analysis population.

**Table 21 – Primary Effectiveness Endpoint in mITT, Safety and Treatment Received Analysis Sets**

| | mITT Analysis Set (N=167) | Safety Analysis Set (n = 177) | Treatment Received Analysis Set (n = 175) |
|---|---|---|---|
| **Posterior Mean** | 0.755 | 0.746 | 0.754 |
| **95% BCI** | (0.685, 0.818) | (0.678, 0.808) | (0.687, 0.817) |

Kaplan-Meier analysis

Figures Figure 2 and Figure 3 present Kaplan-Meier freedom from effectiveness failure for subjects in the Per-Protocol Analysis Set and Treatment Received Analysis Set, respectively. The 12-month Kaplan-Meier estimate of freedom from effectiveness failure was 76.7% (97.5% LCB: 70.1%) in the Per-Protocol Analysis Set and 76.2% (97.5% LCB: 69.7%) in the Treatment Received Analysis Set, both of which are comparable to the posterior mean of 75.9% from the final data.

**Figure 2 – Kaplan-Meier Analysis of Time to First Primary Effectiveness Failures Post Procedure (Per-Protocol Analysis Set, N=166)**

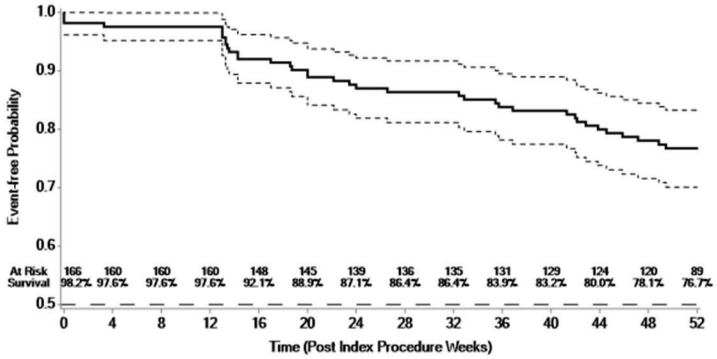
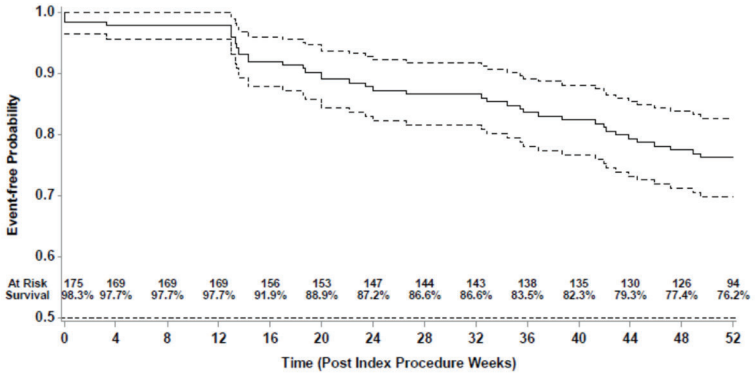


**Figure 3 – Kaplan-Meier Analysis of Time to First Primary Effectiveness Failures Post Procedure (Treatment Received Analysis Set, N = 175)**




Worst-case scenario and tipping point analyses

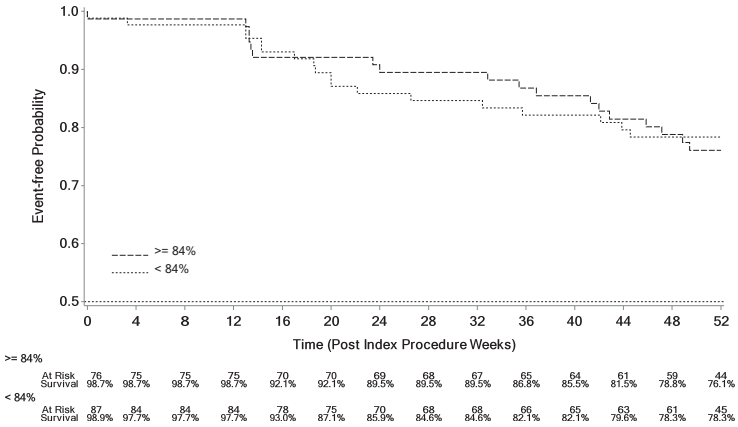
In the worst-case scenario analysis, the 10 subjects missing primary effectiveness endpoint data were considered as having primary effectiveness failure, which resulted in the primary effectiveness success rate of 71.7% in the Per-Protocol Analysis Set, 71.3% in the mITT analysis set and 71.4% in Treatment Received Analysis Set.

Treating all of the 10 subjects with missing outcomes as effectiveness failures one by one, tipping point analyses using a posterior probability threshold of 0.9775 were performed for the primary effectiveness endpoint in the PP, mITT and Treatment Received Analysis Sets to assess the impact of missing outcomes on the primary effectiveness analysis. The posterior distribution was updated each time and the results showed that no tipping point was identified. Therefore, the primary effectiveness performance goal was met in the tipping point analysis.

*Impact of TTM Compliance*

To better understand the impact of TTM compliance on the primary effectiveness results, additional post-hoc Kaplan-Meier analysis on the time to first primary effectiveness failure was performed in subgroups dichotomized at TTM compliance of 84%, a compliance rate reported in a previous PAF ablation trial. The probability of freedom from primary effectiveness failures at 12 months was similar between subjects with TTM compliance rate of < 84% and those ≥ 84% (Figure 4).

**Figure 4 – Kaplan-Meier Analysis of Time to Primary Effectiveness Failures Post Procedure by TTM Compliance (>= 84% vs. <84%) (Per-Protocol Analysis Set, N=166)**




C.6.2 - Acute Procedural Success

Acute procedural success was defined as confirmation of entrance block in all PVs. Off the 166 subjects included in the PP analysis set, two (2) subjects were treated with a non-study catheter for PVI due to CoolFlow Pump malfunction which resulted in replacement of the QDOT catheter with a non-study catheter to complete PVI. These two (2) subjects were excluded from the analysis of acute

procedural success. Acute procedural success was achieved in the remaining 164 subjects (100%, 97.5% LCB: 97.8%) in the PP Analysis Set.

Table 22 presents data on PVI after first encirclement at subject level and at ipsilateral PV level, respectively. Among a total of 164 subjects in the PP Analysis Set who received PVI ablation using the study catheter only (two subjects also treated with a non-study catheter for PVI and discussed above were excluded from the analysis), 94 (57.3%) achieved PVI with first encirclement without acute reconnections. For this analysis, both right-sided PVs and left-sided PVs for the subject had to achieve PVI without acute reconnections. At ipsilateral PV level, PVI was achieved in 72.6% (238/328) of the pulmonary veins (ipsilateral veins) after first encirclement without acute reconnections.

**Table 22 – PVI after First Encirclement at Subject Level and at Ipsilateral PV level (Per-Protocol Subjects Who Received PVI Ablation Using the Study Catheter Only, N=164)**

| Variable | Number of Subjects Underwent Ablation Procedure | Number of Subjects | Rate |
|---|---|---|---|
| PVI after first encirclement | 164 | 94 | 94 / 164 (57.3%) |
| **Variable** | **Number of Targeted Ipsilateral Veins** | **Number of Targeted Ipsilateral Veins with first encirclement** | **Rate** |
| PVI after first encirclement | 328 | 238 | 238 / 328 (72.6%) |

C.6.3. - Incidence of repeat ablation procedures

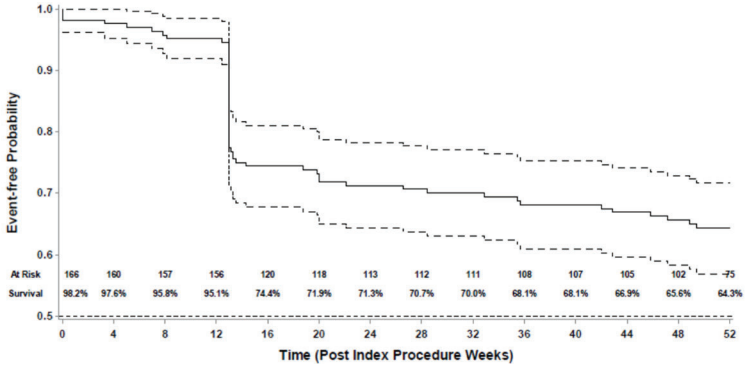
A total of 18 subjects (10.8%) in the Per-Protocol analysis set had one (1) repeat procedure and most (66.7%, 12/18) had their repeat procedure during the evaluation period (Day 91-365). Most subjects (88.9%, 16/18) were treated for AF during the repeat procedure.

C.6.4. - 12-month single procedure success

The 12-Month single procedure success was defined as freedom from documented AF/AFL/AT recurrence (episodes ≥ 30 secs) during the evaluation period after a single ablation and off AADs. Any repeat ablation procedure or Class I or III AAD use for AF/AFL/AT during the evaluation period was deemed effectiveness failure for this endpoint analysis.

Figure 5 presents the Kaplan- Meier analysis of 12-Month single procedure success off Class I/III AAD in the Per Protocol analysis set. The probability of 12-Month single procedure success off Class I/III AADs post blanking was 64.3% in the Per-Protocol analysis set.

**Figure 5 – 12-Month Single Procedure Success off Class I/IIIAADs Post Blanking (Per Protocol Analysis Set, N=166)**



C.6.5 - Quality of Life

The quality of life was measured using the Atrial Fibrillation Effect on Quality-of-Life (AFEQT) at baseline and the 3-, 6-, and 12-month visits.

Figure 6 presents the mean AFEQT composite scores at baseline, 3-, 6-, and 12-month follow up visits in the effectiveness evaluation period, indicating a sustained improvement on the AFEQT scores from 3 months to 12 months post ablation.

**Figure 6 – Mean AFEQT Composite Scores Throughout Study Period (Per-protocol Analysis Set, N=166)**

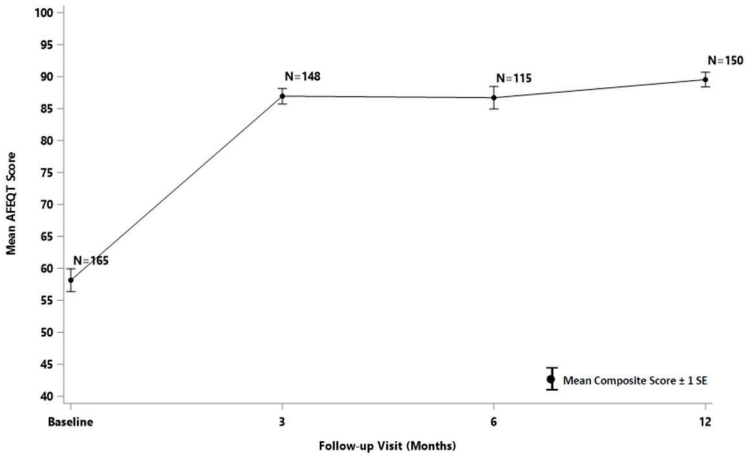
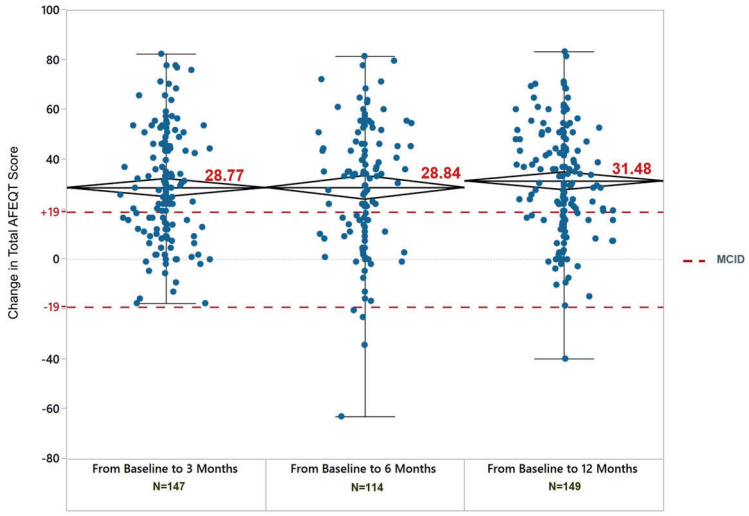



Figure 7 presents change in total AFEQT scores from baseline at 3, 6, and 12 months. The mean change of AFEQT score from baseline to 3 months (28.77) was sustained at 12 months (31.48) and was larger than a clinical important difference of 19 (Dorian et al., 2013) in the majority of subjects.

**Figure 7 – Atrial Fibrillation Effect on Quality of Life (AFEQT) Questionnaire Overall AFEQT Score (Per-Protocol Analysis Set, N=166)**




C.7 - Subgroup Analyses

Subgroup analyses for the primary endpoints were performed , including but not limited to: sex, age,

CHA2DS2-VASc score, and ablation mode used for PVI. Per protocol, a test of independence by sex was performed for both primary endpoints, while for other subgroup analyses only descriptive statistics were presented. The PP Analysis Set and Safety Analysis Set were used for the subgroup analyses of the primary effectiveness endpoint and primary safety endpoint, respectively. The primary effectiveness success rates were similar by age (< 65 vs. ≥ 65 years) and CHA2DS2-VASc score (<=2 vs. >2).

i Gender analysis

The primary endpoints were assessed according to gender. Tables Table 23 and Table 24 summarize the primary effectiveness and safety endpoints by sex in the PP and Safety Analysis Sets, respectively. Effectiveness and safety outcomes were similar between male and female subjects.

**Table 23 – Primary Effectiveness Endpoint by Sex (Per-Protocol Analysis Set, N=166)**

| Primary Effectiveness Endpoint | Male | Female | p-value [1] |
|---|---|---|---|
| Primary Effectiveness Endpoint Success | | | 0.329 |
| n/N | 75 / 95 | 44 / 61 | |
| % | 78.9% | 72.1% | |

[1] Chi-square test

**Table 24 – Primary Safety Endpoint by Sex (Safety Analysis Set, N=177)**

| Primary Safety Endpoint | Male | Female | p-value [1] |
|---|---|---|---|
| Primary AE | | | 0.683 |
| n/N | 3 / 106 | 3 / 70 | |
| % | 2.8% | 4.3% | |

[1] Fisher's exact test

ii Primary Safety by Age (<65 vs. ≥=65)

Table 25 summarizes the primary safety endpoint by age in the Safety Analysis Set. No PAEs were observed in subjects aged <65 years. All PAEs occurred in subjects who were aged ≥65 years. The big difference in the primary safety event rate between the two age groups was likely caused by chance in the study in which a very small number of primary safety events occurred. Previous AF ablation studies (Hao, et al., 2012 and Zado, et al., 2008) reported comparable major complication rates between patients 65 years of age or older and those under age 65.

**Table 25 – Primary Safety Endpoint by Age (Safety Analysis Set, N=177)**

| Primary Safety Endpoint | Age < 65 years | Age ≥ 65 years |
|---|---|---|
| n/N | 0 / 82 | 6 / 94 |
| % | 0.0% | 6.4% |

iii Subgroup analysis of primary endpoints by ablation mode used for PV isolation

Primary effectiveness success was evaluated by ablation mode used for isolating the PVs. Figure 8 presents the Kaplan- Meier analysis of time to primary effectiveness failures by ablation mode used for PVI in the PP Analysis Set. The probabilities of freedom from primary effectiveness failure at 12 months post-procedure were comparable in the 2 groups, QMODE+ for PVI (78.1%) vs. QMODE+ and QMODE for PVI (75.1%).

**Figure 8 – Kaplan-Meier Analysis of Time to First AF/AT/AFL Recurrence Through 12 Months Post Procedure by PV Ablation Mode (Per-Protocol Analysis Set, N=166)**

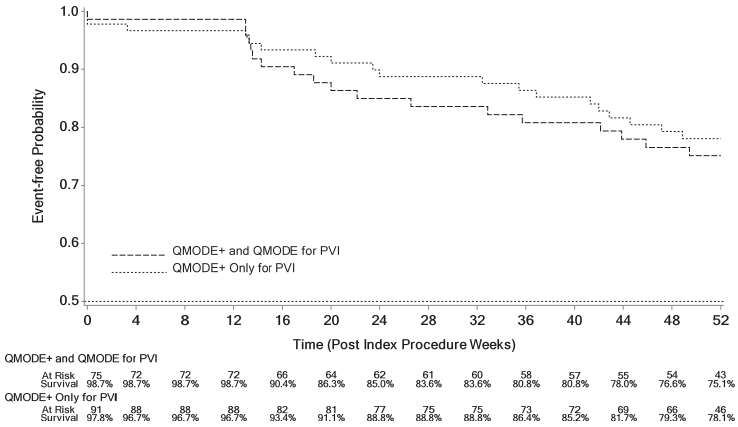



Table 26 summarizes the primary safety outcome by ablation mode used for PVI in the Safety Analysis Set. The PAE rate was similar between the QMODE+ only group and QMODE+ and QMODE group.

**Table 26 – Primary Safety Endpoint by PV Ablation Mode (Safety Analysis Set, N=177)**

| Primary Safety Endpoint | QMODE+ Only | QMODE+ and QMODE |
|---|---|---|
| Primary AE | | |
| n/N | 3 / 95 | 3 / 79 |
| % [1] | 3.2% | 3.8% |

[1] The percentage of subjects with PAEs within each group. Subjects without at least 3 months of follow-up are excluded from the primary safety analysis unless they experienced a PAE.

C.8 - Results in Subjects Who Received Cavo-tricuspid Isthmus Ablation Using Study Catheter

Among a total of 175 subjects who received RF ablation using the study device in the pivotal trial, 47 underwent CTI ablation using the study device only (n = 45), a non-study catheter only (n = 1), or both (n = 1)during the index procedure per study protocol for typical atrial flutter documented either before or during the procedure. Protocol recommended QMODE mode was used to ablate the CTI in all 33 subjects with ablation mode data available and one of the 33 subjects also received ablations in the CTI using the QMODE+ mode.

Among the 46 subjects who received CTI ablation using the study catheter, 44 (95.7%) had bidirectional CTI block confirmed, and the remaining two subjects either did not achieve bidirectional CTI block (n=1) or had missing information about CTI block (n = 1).

Among the 46 subjects who received CTI ablation using the study catheter, none had a primary AE, three (3) had a total of three (3) serious adverse events and 11 had a total of 12 non-serious adverse events within 30 days after a study procedure. None of these serious adverse events or non-serious adverse events was adjudicated as study device-related; while 9 non-serious adverse events were adjudicated as ablation procedure related.

Among the 46 subjects who received CTI ablation using the study catheter, two (2) had documented atrial flutter recurrence during follow-up. The type of recurrent atrial flutter was atypical atrial flutter in one subject and undetermined in another because it was only documented on TTM.

## D. Study Conclusion

The results of the Q-FFICIENCY study demonstrated that there is a reasonable assurance of safety and effectiveness of the QDOT MICRO™ Catheter when used for the treatment of symptomatic drug refractory paroxysmal AF and typical atrial flutter.

## RF ABLATION

For RF ablation the catheter is connected to the CARTO™ 3 System Patient Interface Unit (PIU) via accessory cables, which connect to the RF generator. For setup procedures refer to the User Manual for your CARTO™ 3 Navigation System. For proper RF generator interface, use only a Biosense Webster or compatible interface cable. To complete the electrical circuit, an indifferent electrode must be connected to the indifferent electrode input on the RF generator. Verify that circuit impedance prior to RF ablation is within expected parameters. Verify that the RF generator displays a temperature not above 37°C after the catheter is inserted into the patient and before applying RF power.

## RF GENERATOR OPERATION

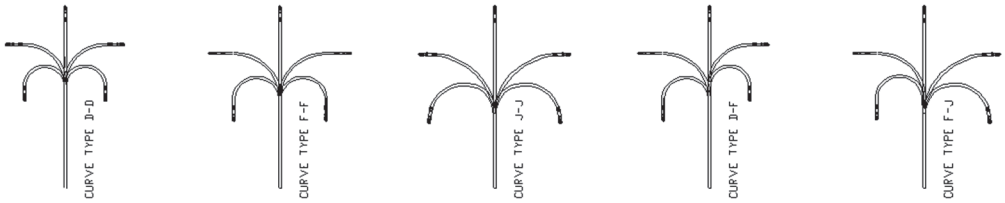
Refer to the applicable RF generator manual for proper connection of the catheter to the generator and for detailed instructions as to generator operation for RF ablation.

RF ablation application parameters will vary depending on the ablation site, the specific conditions present in each procedure and the RF generator control circuitry. Based on data obtained from prior animal and clinical studies, recommended RF application parameters are provided below in the "Directions for Use" and in Table 1. Always monitor temperature and impedance rise when using the QDOT MICRO™ Bi-Directional Navigation Catheter.

## HOW SUPPLIED

- The QDOT MICRO™ Bi-Directional Navigation Catheter is supplied STERILE (EtO).
- The catheter is supplied with a choice of five curve configurations: "DD", "FF", "JJ", "DF", and "FJ" (Figure 9).
- Additional catheter accessory devices are provided separately.

**Figure 9 – Curve Types**




## PACKAGING

The catheter is secured in a two-piece thermoform tray and placed into a Tyvek/Nylon film pouch, sealed, and placed in a box. Both the pouch and thermoform tray are sterile unless the package is damaged or opened.

## STORAGE

Store in a cool, dry, dark place. Storage temperature should be between 5 and 25°C (41 and 77°F).

## STERILIZATION AND USE-BY DATE

This catheter has been sterilized with ethylene oxide gas. Product and package testing have been conducted to support the "Use By" date printed on the product labels. **DO NOT USE** after the "Use By" date.

This device is packaged and sterilized for single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness, or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

## DISPOSAL

Recycle components, or dispose of the product and its residual elements or waste items in accordance with local laws and regulations.

## COMPATIBLE EP NAVIGATION SYSTEM

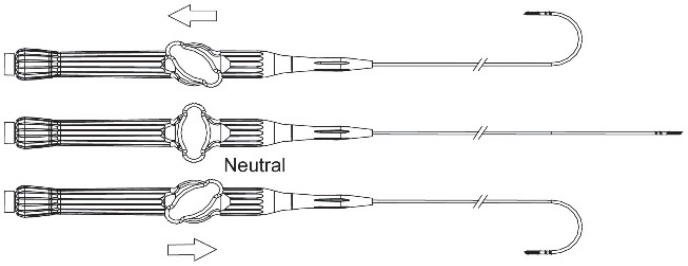
The Biosense Webster QDOT MICRO™ Bi-Directional Navigation Catheter provides location and contact force information only when used with CARTO™ 3 Navigation System. Compatibility with the CARTO™ 3 System has been demonstrated via bench, animal, and clinical testing to confirm that the device is capable of providing accurate location and contact force information when used in accordance with the Instructions for Use.

## DIRECTIONS FOR USE

Please refer to the user manuals for the CARTO™ 3 Navigation System, the irrigation pump, the irrigation tubing, and the generator for instructions on connecting and operating these systems in conjunction with the QDOT MICRO™ Bi-Directional Catheter. Use appropriate Biosense Webster accessory cables to connect the QDOT MICRO™ Bi-Directional Catheter to the appropriate accessory equipment.

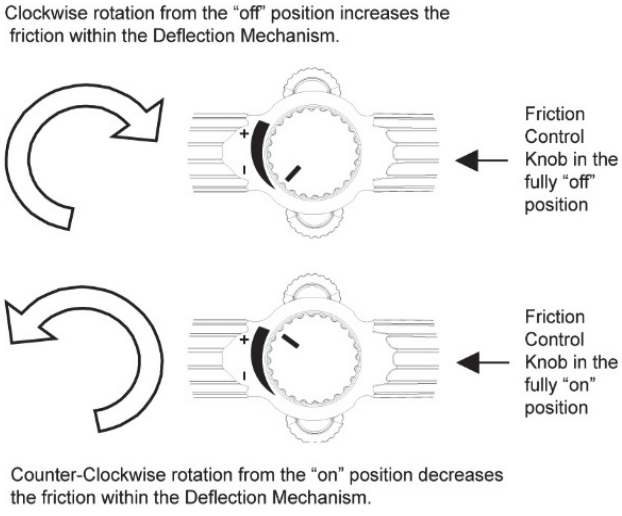
1. Using aseptic technique, remove the catheter from the package and place it in a sterile work area. Inspect the catheter carefully for electrode integrity and overall condition.
2. Use the Rocker Lever to deflect the catheter tip (Figure 10). When the lever is turned out of the neutral position, the tip deflects in the same direction as the lever. The amount of deflection is relative to the amount of lever rotation. To straighten the tip, return the Rocker Lever to neutral position.

**Figure 10 – Deflecting the Catheter Tip with the Rocker Lever**




The handle has an adjustable friction control that allows the operator to use the Rocker Lever and deflecting tip in a “free” state or adjust the friction to where the Rocker Lever and tip curve are “locked” in place (Figure 11). This knob is located on the opposite side of the Rocker Lever. Out of the package, the knob will be in the “off” position, which allows the freest movement for the lever and deflecting tip. The amount of friction increases as the Friction Control Knob is rotated clockwise until it reaches the fully “on” position.

**Figure 11 – Friction Control Knob**



3. Follow standard practice for vessel puncture, guidewire insertion, and guiding sheath use and aspiration per its instructions for use.
4. To verify compatibility between the sheath and catheter, advance the catheter through the sheath prior to insertion. Any sheath < 8.5 F is contraindicated. For compatible sheaths, contact Customer Support or your Biosense Webster representative.
5. Connect the irrigation pump tubing to a room temperature, heparinized (1 IU heparin/ml) normal saline bag using standard safe hospital practices. Open the stopcock on the end of the tubing set and fill the tubing set as slowly as possible. Remove any trapped air and then close the stopcock.
6. Load the irrigation tubing into the pump. Open the stopcock and flush per the irrigation pump instructions until the air is expelled through the open end of the tubing.
7. Connect the irrigation tubing to the Luer fitting of the catheter.
8. Flush the catheter and tubing to ensure purging of trapped air bubbles and to verify irrigation through the tip electrode.
9. Start continuous irrigation with the irrigation pump at the low flow rate.
10. Connect the catheter to the CARTO™ System Patient Interface Unit (PIU) with the appropriate Biosense Webster cables. Connect the PIU to the generator and to the appropriate recording and mapping systems, including the CARTO™ 3 Navigation System, with appropriate interface cables. Use only Biosense Webster interface cables. To complete the electrical circuit, connect an indifferent electrode to the indifferent electrode input on the generator.
11. Insert the QDOT MICRO™ Bi-Directional Catheter via the entrance site.
12. Advance the catheter to the desired area. Use both direct imaging guidance (such as fluoroscopy or ultrasound) and electrograms (EGM) to aid in proper positioning.
13. In order to achieve optimal force reading accuracy and stability, allow the catheter to warm up for 2 minutes after connection to the CARTO™ 3 System, prior to use of the force feedback feature.
14. Zero the contact force reading following insertion into the patient. The tip electrode and the two distal ring electrodes on the catheter tip must be outside of the sheath so that the force sensor is inside the body. Ensure the catheter tip is not in contact with tissue by evaluating the location on fluoroscopy, the CARTO™ System or other direct imaging guidance along with the EGM amplitude and catheter movement. Variations in the force reading at the same rate as the cardiac or respiration cycle may indicate contact with cardiac structures. Once these markers indicate the tip is not in contact, the reading can be zeroed. Refer to the user manual for the CARTO™ 3 System for instructions on how to zero the contact force reading.
15. Zero the contact force reading when moving the catheter from one chamber of the heart to another or upon reinsertion.
16. Verify that the “QDOT MICRO” option is selected on the RF generator. When this option is chosen, the RF generator defaults to the safety parameters established for the QDOT MICRO™ Bi-Directional Navigation Catheter.
17. Table 1 below outlines the recommended ablation parameter settings when using the QDOT MICRO™ Bi-Directional Navigation Catheter for ablation in the atria:

**Table 1: Recommended Ablation Parameter Settings**

| Power Mode | QMODE* | | QMODE+ |
|---|---|---|---|
| Power (W) | 25-35 | 36-50 | 90 |
| Target Electrode Temperature (°C) | 50 | 50 | 60 |
| RF application time (s) | Up to 60 | Up to 60 | 4 |
| Nominal Irrigation flow rate (ml/min)** | 4*** | 15*** | 8 |

* RF applications on the left atrial posterior wall using QMODE should not exceed 35 W in power and 30 sec in duration.

** A minimum flow rate of 2 mL/min during mapping is recommended.

*** The irrigation flow rate is set by the generator and automatically adjusted between 4ml/min or 15ml/min to reach and maintain the set maximum power within the target electrode temperature.

- For the treatment typical atrial flutter, the QMODE is recommended.
- For the treatment of paroxysmal atrial fibrillation, the QMODE+ is recommended as the primary ablation mode for creating pulmonary vein isolation lesions and the QMODE is recommended for applications outside the PV ostia and for touch-up ablations.
- The QMODE power setting allows a maximum power up to 50 W, and the clinical operator may select any combination of power and RF application time, guided by the clinical judgment and expertise of the clinical operator as well as the anatomical area of interest.
- The QMODE+ power setting allows a maximum power up to 90 W, with a maximum RF application time up to 4 seconds. Use caution when overlapping RF ablation points, particularly on the posterior wall. Maintain appropriate contact force within the recommended range. This combination of power and RF application time is optimized for atrial ablation and may be used independently or in conjunction with the QMODE power setting.
- For ablations with any power setting, the clinical operator should monitor commonly used ablation effectiveness parameters like electrogram amplitude reduction and/or impedance drop.

Contact Force (CF) ranges during ablation:

The QFFICIENCY IDE study recommended CF settings to operators for use with the study catheter in both QMODE and QMODE+ as follows:

- CF Working Range: 5-30g

During the study, the overall average CF recorded during a study ablation procedure for all 166 subjects in the Per-Protocol Analyiss set was 15.4 ± 5.2 grams.

18. Do not use this catheter without irrigation flow. Do not alter the irrigation flow rate.
19. Monitor the catheter tip temperature response throughout the procedure to ensure adequate irrigation. If temperature increases very rapidly during RF application, power delivery should be interrupted. The irrigation system must be rechecked prior to restarting RF application. Note: The displayed temperature represents the temperature of the electrode only, not the temperature of the tissue.
20. In the event of a generator cutoff (impedance or temperature), the catheter must be withdrawn and the tip electrode inspected for coagulum before RF energy is reapplied. To remove any coagulum, if present, a sterile gauze pad dampened with sterile saline may be used to gently wipe the tip section clean. Do not scrub or twist the tip electrode as damage to the tip electrode bond may occur and loosen the tip electrode, or damage may also occur to the contact force sensor and affect measurement accuracy. Prior to reinsertion, flush the tip to ensure that the irrigation holes are not plugged.

    If irrigation hole occlusion occurs:

    a. Fill a 1-2 ml syringe with sterile saline and attach it to the stopcock on the end of the tubing set.
    b. Inject the saline from the syringe into the catheter. A uniform flow of fluid should be visible from the tip of the catheter.
    c. Repeat steps a and b, if necessary, until the holes are cleared.
    d. Flush the catheter and tubing per standard technique to ensure purging of trapped air bubbles and to verify that the irrigation holes are patent.
    e. The catheter can now be introduced into the patient.
    f. Zero the catheter following reinsertion into the patient.

    **WARNING: Do not continue use of the catheter if it is still occluded or if it is not functioning properly.**

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Revised: 2023-01

# nGEN™ Generator User Manual

## Catheter Operation

### QDOT MICRO™ Catheter

**Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.**

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EML-1384-02-IFU-02A



Release Date: 9/12/2022

# Table of Contents



# Table of Figures

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# 1 Description of This Operation Manual

This manual contains information specifically applicable to use of the nGEN™ Generator with the Biosense Webster QDOT MICRO™ Catheter. The *nGEN™ Generator User Manual: General Features and Functions* contains information about the nGEN™ Generator that applies regardless of the catheters used with the generator.

# 2 Ablation Modes for the QDOT MICRO™ Catheter

The nGEN™ Generator delivers RF energy using two temperature-controlled ablation modes through the QDOT MICRO™ Catheter. QMODE™ is used for ablation power settings up to 50W; QMODE+™ is used for ablation power settings up to 90W.

QMODE™ uses irrigation flow to maximize power delivery without exceeding target temperature during an ablation. Select a maximum power and a target temperature on the nGEN™ Generator. For maximum power settings greater than 35 W, also select a maximum low flow temperature. Depending on the power setting, the generator changes the pump from high to low flow or from low to high flow to reach and maintain the set maximum power to ensure the tip is within the target temperature range.

- For maximum power settings up to 35 W (the pump starts at low flow): The generator changes the pump from low to high flow to maintain the set maximum power when the temperature exceeds the set target temperature during ablation and the power begins to drop.
- For maximum power settings between 36W and 50W (the pump starts at high flow): The generator changes the pump from high to low flow when the temperature drops below or does not rise above the set maximum low flow temperature during ablation. The change to low flow allows the temperature to rise closer to the target temperature.

QMODE+™ delivers high power in a short ablation session. Select a target temperature and maximum power on the nGEN™ Generator. If the target temperature is reached before the set duration expires, the generator modulates the power to maintain the target temperature.

# 3 Warnings

See the *nGEN™ Generator User Manual: General Features and Functions* and the QDOT MICRO™ Catheter instructions for use for applicable warnings.

# 4 Generator Components

For information about the components provided as part of the nGEN™ Generator, see the *nGEN™ Generator User Manual: General Features and Functions*.

# 5 Catheter Setup and Connections

This section describes how to connect the catheter, and identifies the devices and cables shown in the illustration.

**Figure 1 - QDOT MICRO™ Catheter to CARTO™ System**

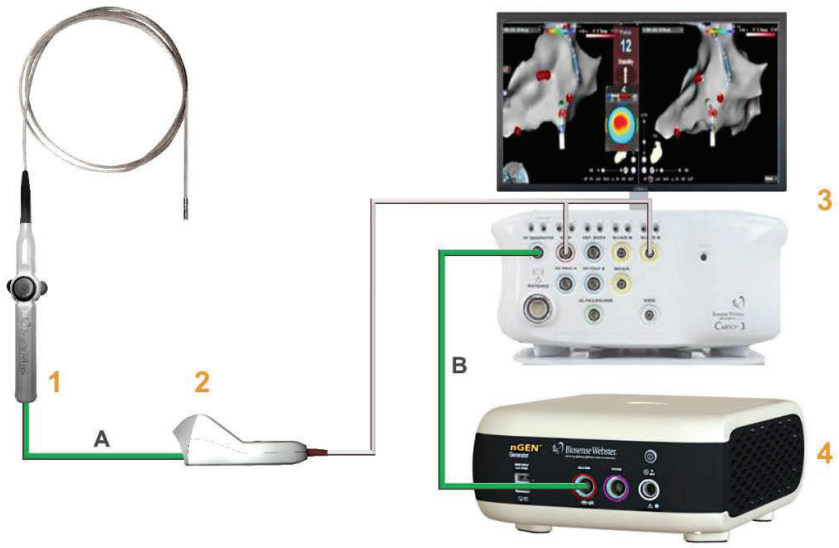



**Table 1 - Devices**

| | | |
|---|---|---|
| **1** | See Note | QDOT MICRO™ Catheter |
| **2** | D140102 | TX eco Cable |
| **3** | FG540000 | CARTO™ System |
| **4** | M685301 | nGEN™ Console |

**Note:** *Contact a Biosense Webster representative for the QDOT MICRO™ Catheter part number.*

**Table 2 - Cables**

| | | |
|---|---|---|
| **A** | D135703 | TX eco EXT Cable |
| **B** | M581007 | Cable TX, nGEN™ Console to CARTO™ System, 3 m (10 ft) |

# 6 Typical Workflow

**Steps**

1. Physically connect all required devices, and selected optional devices, to the generator.
2. Turn on the power supply unit.
3. Turn on the console and monitor(s).
4. At the **Connections** screen, review the device connections.
5. Physically connect all applicable devices to the patient.
6. At the **Presets** screen, confirm the **QDOT MICRO™** selection from the **Catheter** menu, then select or create a preset.
7. At the **Ablation** screen, review the settings. Position the catheter at the first ablation site.
8. Start ablation by pressing the **START** button on either the Primary Monitor or the Secondary Monitor, or by pressing the pedal connected to the Primary Monitor, the Secondary Monitor, or the Console. Press the **STOP** button or release the pedal to stop ablation.

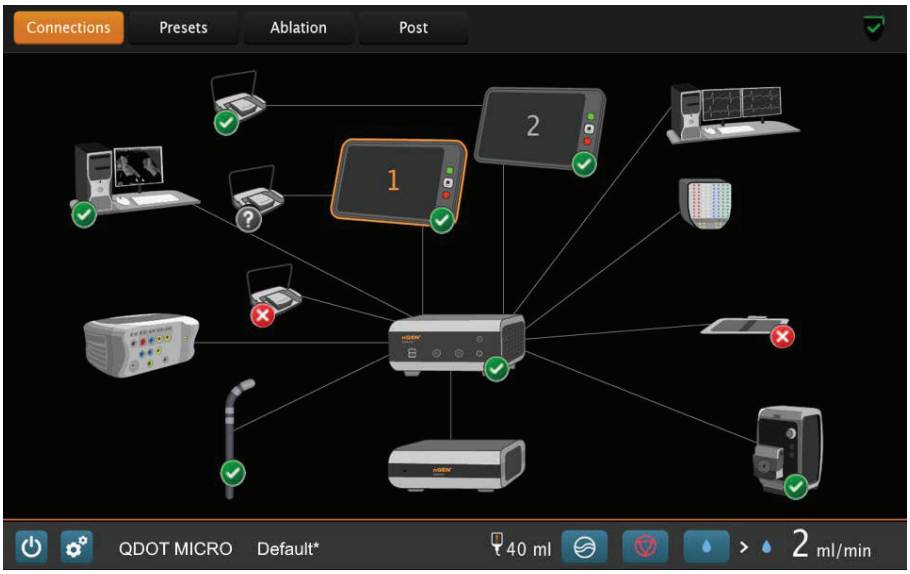
# 7 Generator Screens

For information about the screens that appear regardless of catheter type, see the *nGEN™ Generator User Manual: General Features and Functions*.

## 7.1 Connections Screen: Catheter Dialog Box

The catheter icon on the **Connections** screen indicates only whether a compatible catheter is connected to the nGEN™ Generator. See Figure 1 for details on how to connect the QDOT MICRO™ Catheter to the nGEN™ Generator via the TX eco Cable and CARTO™ System. For information about the **Connections** screen in general, and all other device dialog boxes, see *Section 13.3 Connections Screen, nGEN™ Generator User Manual: General Features and Functions.*

**Figure 2 - Connections Screen: QDOT MICRO™ Catheter**




Press the catheter icon on the **Connections** screen. The **Catheter Type** dialog box appears.

**Table 3 - Catheter Dialog Box**

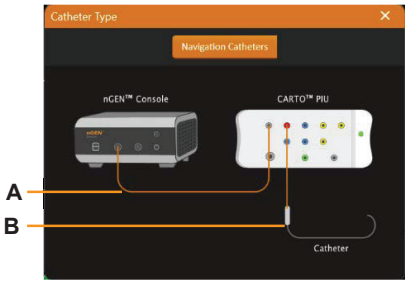
| Button or Field | Description |
|---|---|
|   | • The diagram shows the connection of **Navigation Catheters** to the **nGEN™ Console** and the **CARTO™ PIU**. See *Section 5, Catheter Setup and Connections* for more information. |

**Table 4 - Cables**

| | | |
|---|---|---|
| **A** | M581007 | Cable TX, nGEN™ Console to CARTO™ System, 3 m (10 ft) |
| **B** | D135703 | TX eco EXT Cable |
| Not shown | D140102 | TX eco Cable |

## 7.2 Presets Screen: QDOT MICRO™ Catheter

**Figure 3 - Presets Screen**


**Table 5 - Features on the Presets Screen**

| | |
|---|---|
| 1 | **Undo** button |
| 2 | **New Preset** button |
| 3 | **Delete** button |
| 4 | **Save Preset** button |
| 5 | **Ablation Settings** area |
| 6 | **Irrigation Settings** area |
| 7 | **Preset** Menu |
| 8 | **Catheter** Menu |

### 7.2.1 Preset Overview

- When **QDOT MICRO™** is selected from the **Catheter Menu**, the names of the available presets are displayed in the **Preset** Menu. When a preset name is selected, the settings for that preset are displayed in the **Ablation Settings** area and the **Irrigation Settings** area of the screen.
- If the list is longer than the screen, the grey arrow in the **Next** button becomes white. Press the **Next** button to display the next page of presets. Press the **Previous** button to display the previous page of presets.
- The generator comes with one **QDOT MICRO™** preset named **Default**. Additional presets can be created, or presets can be imported from a USB flash drive.
- Values on the **Presets** screen can be changed. Press the value and the background will become orange. Use the **Control** knob, **Plus** button, or **Minus** button to change the value. The changes are automatically updated.

**Caution:** *Do not press the control knob. Doing so may inadvertently change the **Presets** values.*

### 7.2.2 Preset Settings

The screens below show the fields associated with the QDOT MICRO™ Catheter and are followed by a table that explains each field. The values in the following figures are for illustration only.

**Figure 4 – QDOT MICRO™ Catheter, QMODE™**

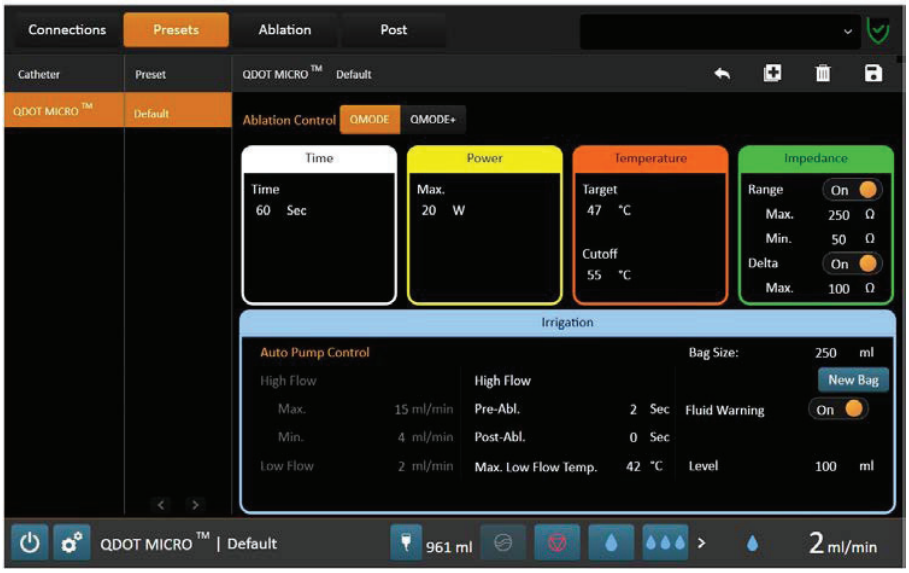


**Figure 5 – QDOT MICRO™ Catheter, QMODE+™**

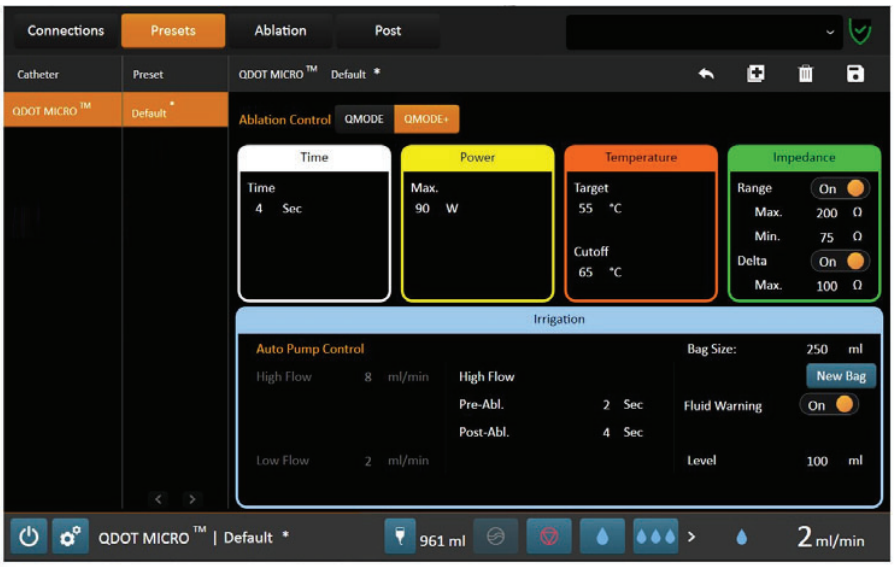



**Table 6 - Preset Settings**

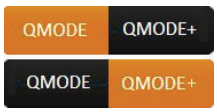
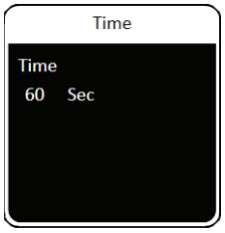
| Field | Setting |
|---|---|
| **Ablation Control**<br>  | • The ablation control displays the ablation mode.<br>• Press **QMODE** for QMODE™ ablation mode or press **QMODE+** for QMODE+™ ablation mode. The selected ablation mode becomes orange. |
| **Time**<br>  | • Change the **Time** value to set the duration of the ablation session.<br>• The value set in this field appears on the **Ablation** screen. |
| **Power**<br>  | • Change the **Max.** value to the maximum power the generator is to deliver during the ablation.<br>• The value set in this field appears on the **Ablation** screen. |

**Table 6 - Preset Settings**

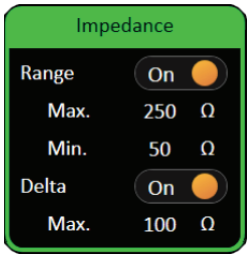
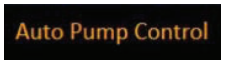
| Field | Setting |
|---|---|
| **Temperature** | |
|  | · Change the **Target** value to the temperature for the generator to reach and maintain during ablation. The value set in this field appears on the **Ablation** screen.<br>· Change the **Cutoff** value to set the temperature for the generator to stop ablation.<br>· The **Target** value must be at least 5°C lower than the **Cutoff** value. When the **Target** value is exactly 5°C lower than the **Cutoff** value, the generator will not allow the **Target** value to be increased unless the **Cutoff** value is increased first to maintain a difference of at least 5°C. |
| **Impedance** | |
|  | **Range**<br>· Press the **On/Off** toggle button to turn on **Range** for the generator to stop the ablation and issue an alarm when the maximum or minimum impedance is reached.<br>· Change the **Max.** and **Min.** values to set the maximum or minimum impedance. It is recommended that impedance during ablation not exceed 250 ohms. The generator will also stop the ablation and issue an alarm if the impedance value becomes infinite (for example, the catheter becomes disconnected from the generator) or the value becomes zero (for example, an internal short).<br>· When **Range** is **Off**, it is not possible to update the **Max.** and **Min.** impedance values.<br>· Press the **On/Off** toggle button to turn on **Delta** for the generator to stop the ablation and issue an alarm when the impedance change exceeds the **Max.** value. |

**Table 6 - Preset Settings**

| Field | Setting |
|---|---|
| **Irrigation** | |
|  | **Auto Pump Control**<br>· **Auto Pump Control** indicates that the pump is being controlled by the generator (see *Section 13.3.6, nGEN™ Pump, nGEN™ Generator User Manual: General Features and Functions*). |
|  | **High Flow**<br>· The **High Flow** values show the irrigation flow rates during ablation and cannot be changed.<br>· When **QMODE™** is selected, the generator changes between the **Max.** and **Min.** flow rates.<br>· Press the **Pre-Abl.** value to set the time to start the high flow before the ablation starts.<br>· Press the **Post-Abl.** value to set the time to maintain the high flow after the ablation ends. |
| | **Low Flow**<br>· The **Low Flow** value shows the irrigation flow rate before the **Pre-Abl.** time and after **Post-Abl. time**. This value cannot be changed. |
| | **Max. Low Flow Temp. (QMODE™ only)**<br>· For **Max. Power** settings between 36W and 50W (the pump starts at high flow), select the **Max. Low Flow Temp.** for the generator to change the pump from high to low flow when the temperature drops below or does not rise above this value during ablation. |
|  | **Bag Size**<br>· Change the **Bag Size:** value to set the size of the irrigation solution bag. The value can be changed in increments of 250 ml. See *Section 12.7, Changing the Irrigation Solution Bag, nGEN™ Generator User Manual: General Features and Functions.*<br>· Press the **New Bag** button to reset the fluid volume calculator. |
|  | **Fluid Warning**<br>· Press the **On/Off** toggle button to turn on **Fluid Warning** for the generator to issue the **Low Fluid Warning** when the **Current Fluid Volume** is below the set **Level** value. |

### 7.2.3 Selecting a Preset

**Steps**

1. Press the **Presets** tab.
2. Verify that **QDOT MICRO™** is selected.
3. Select a preset name. The preset name background turns orange when selected.

### 7.2.4 Changing a Preset: Basic Instructions

**WARNING**
Modifying settings can significantly affect the performance of the nGEN™ Generator. Use clinical judgment and consider patient conditions when modifying the settings.

**Steps**

1. Press the **Presets** tab.
2. Verify that **QDOT MICRO™** is selected.
3. Select a preset name.
4. Change the settings as desired. When a setting is changed, an asterisk appears after the preset name to indicate that a change was made. If the **Default** preset is selected, settings can be changed but not saved, and the **Save Preset** button will be disabled.

5. Press the **Save Preset** button. The **Save Preset** dialog box appears and displays this message:
   *"Are you sure you want to save changes to this preset?"*
6. Press **Yes** or **No**. If **Yes** is pressed, the changes are saved and the asterisk disappears.
7. If a change does not need to be saved, press the **Undo** button. The **Undo Changes** dialog box appears and display this message:
   *"Are you sure you want to undo the changes to this preset?"*
8. Press **Yes** or **No**.

### 7.2.5 Creating a New Preset

**Steps**

1. Press the **Presets** tab.
2. Verify that **QDOT MICRO™** is selected.
3. Select a preset with settings similar to those that will be created for the new preset.
4. Change the settings as desired. When a setting changes, an asterisk appears after the preset name to indicate that a change was made to the selected preset.

5. Press the **New Preset** button. The keyboard will appear.
6. Preset names can have a maximum of 15 characters. Enter a name for the new preset. If that name already exists, the **Save Preset** dialog box appears and displays this message:
   *"[Preset name] already exists. Please choose as different name."*
   Use the Backspace key to delete the name, then enter a new one.
7. Press **Save**.

### 7.2.6 Deleting a Preset

**Steps**

1. Press the **Presets** tab.
2. Select the preset to delete. If the **Default** preset is selected, the **Delete** button will be disabled.
3. Press the **Delete** button. The **Delete Preset** dialog box appears and displays this message:

   *"Are you sure you want to delete this preset?"*
4. Press **Yes**. After a preset is deleted, the deletion cannot be undone.

## 7.3 Ablation Screen: QDOT MICRO™ Catheter

**Steps**

1. After the generator is started, the **Ablation** screen appears.
2. Connect the **QDOT MICRO™** Catheter and the **Ablation** screen displays the settings from the **QDOT MICRO™ Default** preset.
3. If a different preset was previously selected, the **QDOT MICRO™ Connected** dialog box appears and displays this message:

   *"The preset has changed to the Default preset for QDOT MICRO™."*
4. Press **OK**.

**Notes**

- The time, power, and temperature settings on the **Ablation** screen can be changed before and during ablation.
- Changes made in the **Ablation** screen will appear on the **Presets** screen. Changes will be lost if not saved before a procedure ends, or the generator is shut down.
- Data from the ablation sessions is saved in log files that can be exported to a USB flash drive.

**WARNING**

Modifying settings can significantly affect the performance of the nGEN™ Generator. Use clinical judgment and consider patient conditions when modifying the settings.

### 7.3.1 Features on the Ablation Screen

The **Ablation** screen displays temperature, impedance, power, and time values as numbers and graphs.

**Figure 6 - Ablation Screen**


**Table 7 - Features on the Ablation Screen**

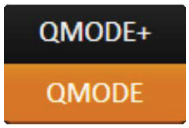
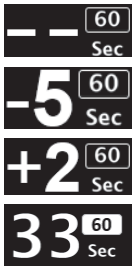
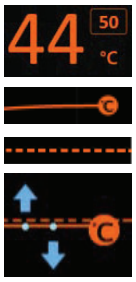
| Feature | Description |
|---|---|
|   | • Press the **QMODE™** or **QMODE+™** to select the ablation mode. The selected mode turns orange. |
| **Time**   | • Two dashes are displayed before and after ablation.<br>• The large white number shows the elapsed ablation time.<br>• When using irrigated catheters, a minus sign before the number indicates the **Pre-Abl.** high flow time and counts to **0** before the ablation starts. A plus sign before the number indicates the **Post-Abl.** high flow time after the ablation ends.<br>• The small white number inside a rectangle shows the ablation duration. This value can be changed before or during ablation by pressing the number. The background will become white. Use the **Control** knob, **Plus** button, or **Minus** button to change the value. |
| **Power**   | • Two dashes are displayed before and after ablation.<br>• The large yellow number shows the real-time power.<br>• The small yellow number inside a rectangle shows the **Max.** power. This value can be changed before or during ablation by pressing the number. The background will become yellow. Use the **Control** knob, **Plus** button, or **Minus** button to change the value.<br>• On the graph, the solid yellow line represents the real-time power and the dashed yellow line represents the **Max. power**. |

**Table 7 - Features on the Ablation Screen**

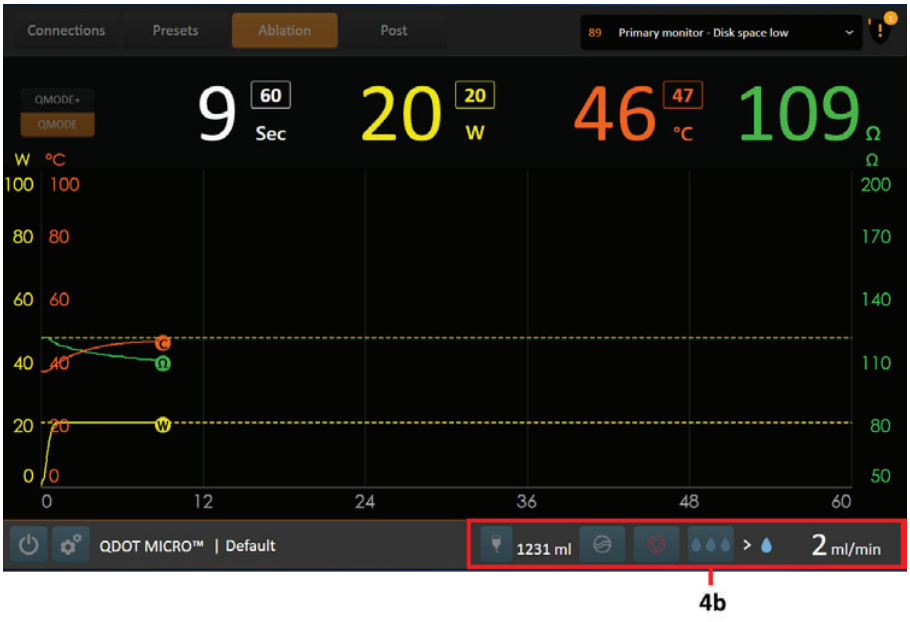
| Feature | Description |
|---|---|
| **Temperature**<br>  <br>(QMODE™) | • The large orange number shows the real-time temperature.<br>• The small orange number inside a rectangle shows the **Target** temperature. This value can be changed before or during ablation by pressing the number. The background will become orange. Use the **Control** knob, **Plus** button, or **Minus** button to change the value.<br>• On the graph, the solid orange line represents the real-time temperature and the dashed orange line represents the **Target** temperature.<br>• On the graph, if **Flow Change Indicator** is selected from the **Ablation Display** screen, the blue arrows and their associated blue dots show when the nGEN™ Pump changes between the **Min.** and **Max. High Flow** settings in QMODE™ ablation mode. See *Section 13.2.1, Ablation Display, nGEN™ Generator User Manual: General Features and Functions.* |
| **Impedance**<br>  | • The green number shows the real-time impedance.<br>• On the graph, a solid green line represents the real-time impedance and the dashed green line represents the impedance value when the ablation session starts. |

**Note:** *When a setting is changed, an asterisk appears after the preset name to indicate that a change was made. Setting changes made on the* ***Ablation*** *screen also appear on the* ***Presets*** *screen.*

## 7.4 Irrigation Control Panel

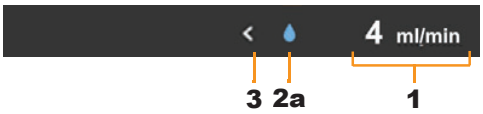
The **Irrigation Control** panel is at the lower right of any screen. Irrigation settings can be changed before ablation, but all buttons are disabled during ablation.

**Figure 7 - Irrigation Control Panel**



The following buttons are displayed.


Press the **Collapse** button to see fewer buttons or the **Expand** button to see more buttons.




If a **Bubble** or **Fluid Level Low** alarm occurs, the display expands automatically to show the alarm.

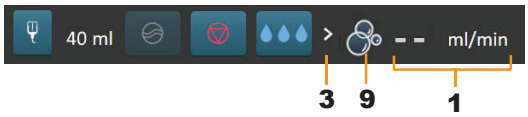


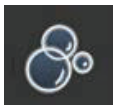

**Table 8 - Irrigation Control Buttons**

| | | |
|---|---|---|
| 1 | **Flow Rate**<br>2 ml/min<br>0 ml/min<br>-- ml/min<br>**Manual Pump Control**<br>M | · The **Flow Rate** button displays the current flow rate. This value is read-only and cannot be changed.<br>· When the generator communicates with the pump and there is no irrigation flow, the **Flow Rate** button displays zero.<br>· When the generator cannot communicate with the pump and there is no irrigation flow, the **Flow Rate** button displays dashed lines.<br>· If **Manual Pump Control** selected, the generator will issue an alarm: *"Pump is in manual mode."*<br>· Return to **Auto Pump Control**. |
| 2a<br>2b | **Low Flow**<br><br>**High Flow** | · The **Low Flow** button indicates when the pump provides irrigation at the set low flow rate.<br>· The **High Flow** button indicates when the pump provides irrigation at the set high flow rate.<br>· The generator automatically changes from low flow rate to high flow rate when the ablation session starts and from high flow rate to low flow rate when the ablation session ends. |
| 3 | **Collapse**<br><br>**Expand** | · Press the **Collapse** button to display only the **Flow Rate** and the **Low Flow** or **High Flow** button.<br>· Press the **Expand** button to display all irrigation buttons.<br><br>**Note:** *The* **Low Flow** *button and the* **High Flow** *button can also be pressed to collapse and expand the display of buttons.* |

**Table 8 - Irrigation Control Buttons**

| | | |
|---|---|---|
| **4a** | **Start Low Flow**<br>  | · If this button is not visible, press the **Expand** button.<br>· Press the **Start Low Flow** button to start low flow on the pump. After the low flow starts, the button changes to the **Start High Flow** button. |
| **4b** | **Start High Flow**<br>  | · Press the **Start High Flow** button to start high flow on the pump. After the high flow starts, the button changes to the **Start Low Flow** button. |
| **5** | **Stop Flow**<br>  | · If this button is not visible, press the **Expand** button.<br>· Press the **Stop Flow** button to stop the irrigation flow. |
| **6** | **Flush**<br>  | **WARNING**<br>Do not flush the catheter when it is in the patient.<br>· If this button is not visible, press the **Expand** button.<br>· Press the **Stop Flow** button to enable the **Flush** button.<br>· Press the **Flush** button to begin flushing the irrigation tubing. The button becomes orange and this message appears:<br>*"To flush, press and hold the **Control** knob on the monitor. Release the knob to stop flushing."*<br>· Press and hold the **Control** knob on the monitor to flush the irrigation tubing.<br>· Release the **Control** knob to stop flushing.<br>· Flushing cannot be performed during ablation.<br>· When it is not possible to flush, the button is disabled (grey). |
| **7** | **Current Fluid Volume**<br>  | · The **Current Fluid Volume** displays the amount of fluid in the irrigation solution bag. |
| **8a** | **Reset Bag**<br>  <br>  | · If the **Reset Bag** button is not visible, press the **Expand** button.<br>· Press the **Reset Bag** button to change the irrigation solution bag. The button changes to orange and the **Bag Size:** and **New Bag** button appear. Change the **Bag Size:** value to the set the size of the irrigation solution bag in increments of 250 ml. Press the **New Bag** button to reset the fluid volume calculator. See *Section 12.7, Changing the Irrigation Fluid Bag, nGEN™ Generator User Manual: General Features and Functions*. |
| **8b** | **Low Fluid Warning**<br>  | · The **Low Fluid Warning** button appears when **Current Fluid Volume** drops below the set **Level** value. If on the **Presets** screen, the **Fluid Warning** field is selected **On**, an alarm message will appear.<br><br>**Note:** *The **8a** and **8b** buttons appear together on the figure above for illustration; the **Irrigation Control** panel will display either the **8a** or **8b** icon, but not both at the same time.* |

**Table 8 - Irrigation Control Buttons**

| | | |
|---|---|---|
| 9 | **Bubbles**<br>  | • The **Bubbles** alarm displays when the pump detects bubbles in the irrigation tubing set.<br>• If a bubble error occurs, the irrigation tubing must be flushed. Remove the catheter from the patient or close the stopcock to the catheter, then press the **Flush** button. The **Flush** dialog box appears and displays this message:<br>*"To flush, press and hold the **Control** knob on the monitor. Release the knob to stop flushing."*<br>• Press and hold the knob to flush and release the **Control** knob after the **Bubbles** alarm disappears. Flushing cannot be performed during ablation. |

## 7.5 Post Screen: QDOT MICRO™ Catheter

The **Post** screen displays data about the entire ablation procedure or a specific ablation session. The data remains available on the **Post** screen until a selection is made from the **Shut Down** menu. The data is then deleted from the **Post** screen but is saved in a log file.

**Figure 8 - Post Screen: Ablation Procedure Summary**

**Figure 9 - Post Screen: Ablation Session Information – Data**


**Figure 10 - Post Screen: Ablation Session Information – Graph**


## Steps

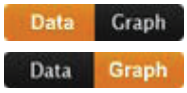
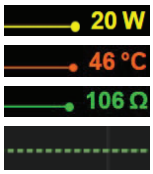
(74) 4

1. Press the **Post** tab.
2. Press the **Procedure Summary** button or an **Ablation Session** button.

**Table 9 - Post Screen Fields**

| Feature | Description |
|---|---|
| **Procedure Summary**<br>  | • The number on the **Procedure Summary** button indicates the total number of ablation sessions in the procedure. Press the button to display the **Procedure Summary**.<br>• The background of the **Procedure Summary** button changes from black to orange when it is selected, and the procedure information is displayed. |
| **Total Time**<br>(Procedure Summary) | • The **Total Time** field displays the total duration of all ablation sessions in the procedure in hours/minutes/seconds (00:00:00). |
| **Start Time** | • An ablation procedure starts when **End Procedure** or **Reload Software** is selected from the **Shut Down** menu.<br>• The **Start Time** field in the ablation session area displays the time that the ablation session started.<br>• The **Start Time** field in the procedure summary area displays the time that the ablation procedure started. |
| **Date**<br>(Procedure Summary) | • The **Date** field displays the date that the procedure was started. |
| **Total Irrigation**<br>(Procedure summary) | • The **Total Irrigation** field displays the amount of fluid that was delivered during the ablation procedure.<br>• The number represents the total amount of fluid used during the ablation procedure, including during low flow and during pre-ablation and post-ablation high flow. It does not include fluid delivered during flushing. |
| **Ablation Session**<br>  | • The **Ablation Session** button represents the individual ablation sessions. Press a number to view the information for the corresponding ablation session.<br>• The background of the **Ablation Session** button changes from black to orange when it is selected, and the corresponding ablation session information is displayed. |
| **Next** **Previous**<br>  | • Press the **Next** button or the **Previous** button to display ablation numbers that are not visible. |
| **Total Time**<br>(Ablation session) | • The **Total Time** field displays the duration of the ablation session in minutes/seconds (MM:SS). |
|  | • The yellow **Maximum**, **Average**, and **Total** fields display the maximum, average, and total power reached during the ablation session or ablation procedure. |
|  | • The orange **Maximum** and **Average** fields display the maximum and average temperature reached during the ablation session or ablation procedure. |

**Table 9 - Post Screen Fields**

| Feature | Description |
|---|---|
|  | · The green **Maximum** and **Minimum** fields display the maximum and minimum impedance reached during the ablation session or ablation procedure.<br>· The **Drop** field displays the impedance drop during the ablation session. |
| **Irrigation**<br>(Ablation session ) | · The **Irrigation** field displays the amount of fluid delivered during the ablation session.<br>· The number represents the total amount of fluid used during the ablation session, including during low flow and during pre-ablation and post-ablation high flow. It does not include fluid delivered during flushing. |
| **Stop Reason**<br>(Ablation session) | · The **Stop Reason** field displays the reason why the ablation session stopped. |
| **Catheter Type**<br>(Ablation session) | · The **Catheter Type** field displays the catheter type that was used during the ablation session. |
|  <br>(Ablation session) | · The **Data/Graph** button is a toggle button. The selected button has an orange background.<br>· The orange **Data** button indicates that the data for the ablation session is displayed.<br>· The orange **Graph** button indicates that a graph of the ablation session is displayed. |
|  <br>(Ablation session) | · The yellow line and number represent the power reached as the ablation session progressed.<br>· The orange line and number represent the temperature reached as the ablation session progressed.<br>· The solid green line and number represent the impedance reached as the ablation session progressed.<br>· The dashed green line represents the impedance value when the ablation starts.<br>· Press on any graph line, then use the **Control** knob to see the power, temperature, and impedance values at any point during the selected ablation session. |

# 8 Technical Data

## 8.1 Output Specifications: QDOT MICRO™ Catheter

**Figure 11 - Output Specifications**

Power Level  Accuracy Tolerance

Load Impedance: 50 - 250 Ω

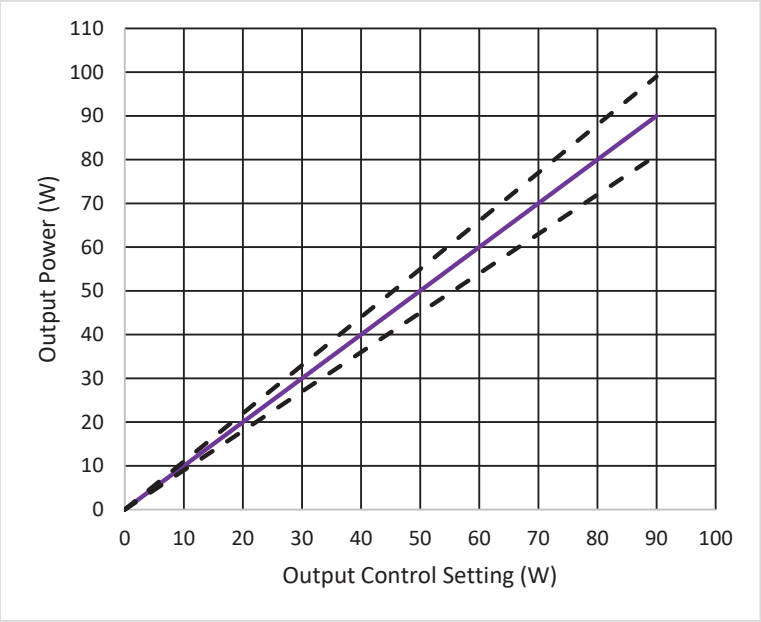
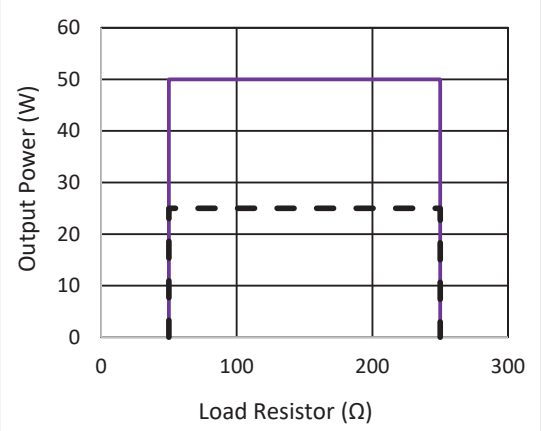


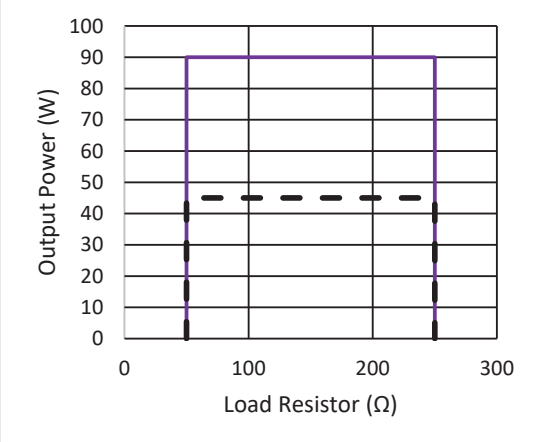

**Figure 12 – Output Specifications - QMODE™ and QMODE+™ Ablation Modes**

**Full power  Half power**

QMODE™ Ablation Mode




QMODE+™ Ablation Mode



# 9 Troubleshooting

The Alarm Messages table explains each alarm message that may appear when a QDOT MICRO™ Catheter is used.

**Table 10 - QDOT MICRO™ Catheter Alarm Messages**

| Message<br>· Reasons | What To Do | Icon | Alarm Tone |
|---|---|---|---|
| **CARTO™ - catheter error**<br>· The generator has received a message from the CARTO™ System. | · Check catheter error message(s) on CARTO™ System. | ✕ | ✓ |
| **CARTO™ - communication error**<br>· There is a problem with the communication between the CARTO™ System and the nGEN™ Generator. | · Verify that the Ethernet cable from the CARTO™ System Workstation to the nGEN™ Console is properly connected.<br>· Verify that the Ethernet cable is not damaged.<br>· Reload the software on the monitor(s).<br>· Reload the software on the CARTO™ System.<br>· If the problem persists, turn the console off and then on. Restart the monitor(s).<br>· If the problem persists, replace the cable. | ✕ | ✓ |
| **Electrode - delta impedance too high**<br>· The impedance change exceeded the maximum impedance delta value set in the preset. | · Verify that the maximum impedance delta setting in the selected preset is appropriate.<br>· Consider possible clinical reasons such as a steam pop or the catheter being pushed suddenly into the tissue.<br>· Restart the console and monitor(s). | ✕ | ✓ |
| **Electrode - impedance too high**<br>· The impedance exceeded the maximum impedance value set in the preset. | · Verify that the maximum impedance setting in the selected preset is appropriate.<br>· Verify that the catheter is properly inserted in the body and is out of the sheath.<br>· Disconnect the indifferent electrode from the console, then reconnect it.<br>· Disconnect the catheter cable from the console or from the CARTO™ PIU, then reconnect it.<br>· If the catheter cable is connected to the CARTO™ PIU, verify that the cable from the CARTO™ PIU to the console is properly connected.<br>· Improve the contact of the indifferent electrode with the patient's skin or use a different indifferent electrode.<br>· Consider applying an indifferent electrode to a different place on the patient's body to avoid oil, hair, and dirt that increase the impedance. | ✕ | ✓ |

**Table 10 - QDOT MICRO™ Catheter Alarm Messages**

| Message<br>· Reasons | What To Do | Icon | Alarm Tone |
|---|---|---|---|
| **Electrode - impedance too low**<br>· The impedance was below the minimum impedance value set in the preset. Rarely, such as in pediatric cases, the patient has low body impedance and there is no problem. | · Verify that the minimum impedance setting in the selected preset is appropriate.<br>· Restart the console and monitor(s).<br>· Replace the sterile catheter cable or the cable between the console and the CARTO™ PIU.<br>· Replace the catheter and/or catheter cable(s). | ✕ | ✓ |
| **Electrode - power too high**<br>· During ablation, the generator delivered higher power than the power value set in the preset.<br>· The console has an internal error. | · Turn off the console. Let it cool down, then turn it on again.<br>· Contact Customer Support even if the problem is resolved. | ✕ | ✓ |
| **Electrode - power too low**<br>· During ablation, the generator delivered lower power than the power value set in the preset.<br>The console has an internal error. | · Turn off the console. Let it cool down, then turn it on again.<br>· Contact Customer Support even if the problem is resolved. | ✕ | ✓ |
| **Electrode – temperature invalid**<br>· When the temperature is invalid and not displayed on the screen. | · Verify that a QDOT MICRO™ Catheter is being used and is properly connected.<br>· Verify that TX cable M581007 is being used and is properly connected to the Console and the CARTO™ System. | ✕ | ✓ |
| **Electrode - temperature not decreasing**<br>· The temperature of the catheter's electrode is above the target temperature for longer than the time that is predefined in the system. | · Verify that the temperature settings in the selected preset are appropriate.<br>· Reposition the catheter.<br>· Check irrigation flow (lines, catheter tip, pump).<br>· Restart the console and the monitor(s).<br>· Replace the catheter and/or the catheter cable(s). | ✕ | ✓ |
| **Electrode - temperature slope too high**<br>· The temperature of the ablation electrode increased suddenly.<br>· The temperature sensor(s) in the catheter intermittently disconnected and reconnected.<br>· The wires in the catheter cable(s) intermittently disconnected and reconnected. | · Reposition the catheter.<br>· Check irrigation flow (lines, catheter tip, pump).<br>· Restart the console and the monitor(s).<br>· Replace the catheter and/or the catheter cable(s). | ✕ | ✓ |

**Table 10 - QDOT MICRO™ Catheter Alarm Messages**

| Message<br>· Reasons | What To Do | Icon | Alarm Tone |
|---|---|---|---|
| **Electrode - temperature too high**<br>· The temperature of the catheter ablation electrode exceeded the temperature cutoff value set in the preset. Possible reasons are:<br>  · The ablation electrode is too hot.<br>  · The cutoff value is too low. | · Wait a few seconds for the temperature to drop before restarting ablation.<br>· Consider possible clinical reasons for the ablation electrode to overheat.<br>· Restart the console and the monitor(s). | ✕ | ✓ |
| **Electrode - temperature too low**<br>· The generator does not recognize a valid temperature reading. | · Verify that the catheter and catheter cable(s) are compatible with the generator.<br>· Restart the console and the monitor(s).<br>· Replace the catheter and/or the catheter cable(s). | ✕ | ✓ |

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Revised: 2022-08

EML138402IFU02A

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# Sterile Interface Cables

**Symbol Definitions**

Medical Device

Sterilized using ethylene oxide

Catalog number

US catalog number

Batch code

Unique Device Identifier


Manufacturer


Date of manufacture

Authorized Representative in the European Community


Packaging unit


Single sterile barrier system with protective packaging outside


Use-by date


Caution


Consult instructions for use

e-IFU indicator

Do not use if package is damaged

Do not use if package is opened

Keep away from sunlight

Keep dry

Temperature limit

℞ only

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Waste Electrical and Electronic Equipment Directive (WEEE)—Dispose of in a manner consistent with required EU Directives in your local jurisdiction.

Pin Connector

ASSEMBLED | MEXICO

Assembled in Mexico

## Sterile Interface Cables

**Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.**

### INDICATIONS FOR USE

These cables provide a means to connect a Biosense Webster electrophysiology catheter to the appropriate equipment. The cables may be reused subject to the cleaning and sterilization restrictions in this document.

**Table 1 – Cables**

| Cable Name | Purpose | Catalog Numbers | Manufacturing Numbers |
|---|---|---|---|
| TX *eco* EXT Cable | Connects a therapeutic “eco” catheter to a CARTO™ 3 System. | D135703 | D-1357-03-S |
| Interface Cable, CELSIUS™ Catheter to nGEN™ Generator | Connects a CELSIUS™ Catheter to an nGEN™ Generator. | D133703 | D-1337-03-S |

### CONTRAINDICATIONS

There are no known contraindications for these cables.

### PATIENT TARGET GROUP

These cables are targeted at patients who have been diagnosed with cardiac arrythmias and are undergoing an electrophysiology procedure.

### INTENDED USERS

The intended users of these cables are appropriately trained personnel in a fully equipped electrophysiology laboratory.

### CLINICAL BENEFIT

These cables provide a means to connect a Biosense Webster electrophysiology catheter, external reference patch, or sheath to the appropriate equipment.

### DIRECTIONS FOR USE

1. Do not use the cable after the use-by date on the product label.
2. Before using or reusing the cable, visually inspect it for damage such as crushed or elongated sections, cuts, kinks, or nicks. If the cable is damaged, do not use the cable and dispose of it per the “DISPOSAL” section below.
3. Connect each cable to the proper equipment by referring to the connector designations at each end of the cable.
4. Follow the instructions in the “CLEANING AND STERILIZATION,” “STORAGE,” and “DISPOSAL” sections below.

### CLEANING AND STERILIZATION

These cables are provided sterile. They may be resterilized as described below. These cables meet the requirements of the ANSI/AAMI EC53-2013.

**Table 2 – Cleaning and Sterilization**

| | |
|---|---|
| **Warnings and Precautions** | 1. Ensure proper cable connection by referring to the connector designations at each end of the cable.<br>2. Do not use the cable after the use-by date on the product label.<br>3. Do not immerse the cable connectors in liquid. Do not wipe the cable connectors with liquid. The presence of liquid inside the connectors may result in adverse effects, including improper functioning (such as noisy signals or signal degradation) or arcing of electricity between the connector pins, which can lead to patient injury.<br>4. Do not expose the cable to organic solvents because they may damage the cable.<br>5. Patient or operator injury may result from improper handling, improper connection, or improper use of the cable.<br>6. To prevent damage, store the cable in a clean and secure area.<br>7. If a break occurs in the cable wire or if the cable becomes otherwise electrically discontinuous, arcing may occur in the patient-return or active circuit and may burn the patient or create a fire.<br>8. Failure to properly clean the cable could lead to inadequate resterilization.<br>9. Do not use radiation sterilization because it will damage the cable.<br>10. When sterilizing the cables, do not exceed 140°C because temperatures higher than 140°C may damage the cable.<br>11. Automated cleaning of the cable is not recommended because fluid may enter the connectors and leave moisture or residue in or on the connectors. Resulting adverse effects may include improper functioning (such as noisy signals or signal degradation) or arcing of electricity between the connector pins, which can lead to patient injury. |
| **Limitations on Cleaning and Sterilization** | Clean and sterilize the cable after each use. The maximum number of sterilization cycles is specified in Table 3. Exceeding the specified number of sterilization cycles may impair the proper functioning of the cable. |

<table>
<tr><td>Initial Treatment at Point of Use</td><td>There are no requirements for initial treatment at point of use.</td></tr>
<tr><td>Containment and Transportation</td><td>Place the cable in a clean biohazard bag after use for subsequent cleaning, disinfection, and sterilization. Clean, disinfect, and sterilize the cable as soon as it is reasonably practical after use.</td></tr>
<tr><td>Preparation before Cleaning</td><td>Visually inspect the cable for any damage such as crushed or elongated sections, cuts, kinks, or nicks. If damage is observed, do not use the cable and dispose of it per the “Disposal” section below.</td></tr>
<tr><td>Cleaning: Automated</td><td>Automated cleaning of the cable is not recommended because fluid may enter the connectors and leave moisture or residue in or on the connectors. Resulting adverse effects may include improper functioning (such as noisy signals or signal degradation) or arcing of electricity between the connector pins, which can lead to patient injury.</td></tr>
<tr><td>Cleaning: Manual</td><td>1. Wear sterile gloves while handling the cable.<br>2. Using a wipe*, use a twisting motion to wipe the entire surface of the cable, but not the cable connectors, to remove soil. Pay particular attention to complex cable features (such as non-smooth areas, joints, and crevices).<br>3. Using another wipe*, use a twisting motion to thoroughly wipe the entire surface of the cable to remove soil.<br>4. Visually inspect the cable to ensure there is no visible soil. Additional wipes may be used to remove any visible soil.<br>5. Leave the cable in ambient conditions until it is visibly dry.<br>6. When the cable is dry, visually inspect the entire surface of the cable in adequate lighting to ensure complete removal of visible soil.<br>*Recommended Wipes:<br>CaviWipes™ or any other wipes with the chemical composition indicated in the table below may be used.
<table>
<tr><th>Chemical Composition</th><th>% of Chemical</th></tr>
<tr><td>Isopropanol</td><td>17.2%</td></tr>
<tr><td>Diisobutylphenoxyethoxyethyldimethylbenzyl ammonium chloride</td><td>0.28%</td></tr>
</table></td></tr>
<tr><td>Disinfection</td><td>1. Wear sterile gloves while handling the cable.<br>2. Ensure manual cleaning (see the “Cleaning: Manual” instructions in this table) is performed before disinfection.<br>3. Using a wipe*, use a twisting motion to thoroughly wipe the entire surface of the cable. Pay particular attention to complex cable features (such as non-smooth areas, joints, and crevices).<br>4. Allow the surface of the cable to remain visibly wet for 3 minutes at room temperature (approximately 68°F/20°C).<br>5. Additional wipes may be used to ensure that the cable remains visibly wet for 3 minutes.<br>6. Leave the cable in ambient conditions until it is visibly dry.<br>7. Visually inspect the entire surface of the cable in adequate lighting to ensure the cable is visibly clean.<br>*Recommended Wipes:<br>CaviWipes™ or any other wipes with the chemical composition indicated in the table below may be used.
<table>
<tr><th>Chemical Composition</th><th>% of Chemical</th></tr>
<tr><td>Isopropanol</td><td>17.2%</td></tr>
<tr><td>Diisobutylphenoxyethoxyethyldimethylbenzyl ammonium chloride</td><td>0.28%</td></tr>
</table></td></tr>
<tr><td>Drying</td><td>Drying is performed as part of the disinfection process (see the “Disinfection” instructions in this table).</td></tr>
<tr><td>Maintenance, Inspection, and Testing</td><td>Before packaging, visually inspect the cable. If visible soil is present, repeat the “Cleaning: Manual” and “Disinfection” instructions in this table. If there is evidence of damage, do not use the cable and dispose of it per the “Disposal” section below.</td></tr>
<tr><td>Packaging</td><td>If the cable is stored after cleaning and disinfection, place it in a breathable pouch that is approved by the FDA and/or by local authorities. Coil the cable into a loop when placing it into the pouch. Do not fold the cable because doing so may break the cable. Use a pouch large enough to prevent stress to the pouch seams and to prevent excessive bending of the cable. A pouch size of 19 cm x 33 cm (7.5" x 13") or larger is recommended. For storage conditions, refer to the “Storage” section below.</td></tr>
<tr><td>Resterilization</td><td>See Table 3 and Table 4 for resterilization methods, parameters, and the maximum number of sterilization cycles. Resterilize the cable after each use.</td></tr>
</table>

The instructions provided above have been validated by the medical device manufacturer as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing as performed (using equipment, materials, and personnel in the processing facility) achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

**Table 3 – Validated Resterilization Methods for Each Cable**

| Maximum Number of EtO Resterilization Cycles | Maximum Number of Steam Resterilization Cycles | Cable Name | Cable Catalog Numbers |
|---|---|---|---|
| 20X | 20X | TX *eco* EXT Cable | D135703 |
| | | Interface Cable, CELSIUS™ Catheter to nGEN™ Generator | D133703 |

**Table 4 – Resterilization Parameters for Cables**

| | Exposure Temperature | Exposure Time | Minimum Drying Times | Gas Concentration | Humidity (RH) | Accommodation/ Aeration Time at 55°C |
|---|---|---|---|---|---|---|
| **Gravity Steam Resterilization** | 121°C (250°F) | 30 min | 15 - 30 min | --- | --- | --- |
| | 132°C (270°F) | 15 min | 15 - 30 min | --- | --- | --- |
| | 135°C (275°F) | 10 min | 30 min | --- | --- | --- |
| **100% EtO Gas Resterilization** | 55°C (131°F) | 1 hr | --- | 725 mg/L | 30% - 80% | 12 hr |

## STORAGE
Refer to the product label for recommended storage conditions.

## DISPOSAL
Recycle components or dispose of the product and its residual elements or waste items in accordance with local laws and regulations.

## REPORTING INCIDENTS
Per regulation 2017/745/EU on medical devices, if this device is used in the European Union (or in a country with an identical regime) and a serious incident occurs during the use of this device or as a result of use of this device, report the incident to the manufacturer and/or its authorized representative and to your national authority.

## ADVERSE REACTIONS
A number of adverse reactions have been documented for electrophysiology procedures including:

heart block, pulmonary vein stenosis, esophageal fistula and/or injury, stroke (cerebrovascular accident), other arrhythmias (outside diagnosis), life threatening arrhythmias, myocardial infarction, cardiac perforation, pericardial effusion, cardiac tamponade, thrombosis, embolism, pulmonary embolism, air embolism, valvular damage, phrenic nerve injury, vagal nerve injury, pericarditis, coronary artery stenosis, vessel perforation (peripheral and/or central), soft tissue injury, persistent atrial communication, device related infection, embolization of components, device entrapment, surgical intervention (additional), skin burns, and localized skin reaction.

The following complications associated with cardiac catheterization have also been reported in the literature:

major bleed, hematoma, reaction to medications, allergic reaction, vascular access complication, damage to vasculature, implanted device interactions, renal artery stenosis, pneumothorax, ST segment changes, fluid overload, urinary catheter complications, hypotension, sepsis, wound infection, respiratory failure, heart injury, renal injury, heart failure, cardiac arrest and death.

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## ELECTRONIC INSTRUCTIONS FOR USE
This document is available at www.e-ifu.com.

NOTES

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Revised: 2022-05

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CE 2797

# TX *eco* Cable

**Symbol Definitions / Определения на символите / Definice symbolů / Symboldefinitioner / Symboldefinitionen / Ορισμοί συμβόλων / Definiciones de símbolos / Sümbolite tähendused / Symbolien selitykset / Définitions des symboles / Opis simbola / A szimbólumok magyarázata / Definisi Simbol / Definizioni dei simboli / 기호 - 정의 / Simbolių apibrėžtys / Simbolu definīcijas / Дефиниции за символите / Definitie van symbolen / Symboldefinisjoner / Definicje symboli / Definições dos símbolos / Defini iile simbolurilor / Определение символов / Definície symbolov / Definicije simbolov / Дефиниције симбола / Symbolförklaringar / Sembol Tanımları / 标识定义 / 符號定義**

Following definitions are for reference only. Please refer to the product label for applicable usage. / Следващите определения са само за справка. Моля, направете справка в етикета на изделието относно използването му. / Níže uvedená vysv tlení jsou pouze informativní. Příslušné symboly jsou použity na štítku výrobku. / Følgende definitioner er kun til reference. Der henvises til produktmærkningen for gældende anvendelser. / Die folgenden Definitionen dienen ausschließlich zu Referenzzwecken. Ziehen Sie bitte das Produktetikett für die geeignete Verwendung zu Rate. / Οι παρακάτω ορισμοί προ ρίζονται μόν για αναφορά. Παρακαλ ύμε ανατρέξτε στην ετικέτα του προϊόντος για την ισχύουσα χρήση. / Las definiciones siguientes son solo para referencia. Consulte en la etiqueta del producto el uso pertinente. / Järgmised definitsioonid on ainult viitamiseks. Vaadake sobiva kasutamise teavet toote sildilt. / Seuraavat määritykset on annettu ainoastaan merkkien selitystarkoituksessa. Katso soveltuva käyttö tuotteen etiketistä. / Les définitions suivantes sont fournies à titre de référence uniquement. Veuillez vous référer à l'étiquette du produit pour consulter l'utilisation applicable. / Navedene definicije služe samo kao referenca. Za točnu primjenu proučite naljepnicu na proizvodu. / A következő magyarázatok kizárólag a tájékoztatást szolgálják. Az alkalmazandó felhasználás tekintetében kérjük, olvassa el a termék címkéjét. / Definisi berikut hanya untuk referensi. Harap lihat label pada produk untuk penggunaan yang berlaku. / Le seguenti definizioni sono solo a scopo di riferimento. Fare riferimento all'etichetta del prodotto per l'utilizzo pertinente. / 다음 정의는 참고용일 뿐입니다. 해당 사용에 대해서는 제품 라벨을 참조하십시오. / Pateiktos apibrėžtys yra tik nurodomojo pobūdžio. Tinkamo naudojimo aprašą žr. gaminio etiketėje. / Šīs definīcijas ir tikai atsaucei. Piemērojamai lietošanai, lūdzu, skatiet produkta etiķeti. / Следниве дефиниции служат само како референца. Прочитајте ја етикетата на производот за информации за соодветна употреба. / De hierna genoemde definities zijn uitsluitend bedoeld als referentie. Raadpleeg het productetiket voor de gebruikstoepassingen. / Følgende definisjoner er kun for referanse. Se produktetiketten for passende bruk. / Poniższe definicje przedstawiono wyłącznie dla celów informacyjnych. Informacje na temat użycia można znaleźć na etykiecie produktu. / As definições que se seguem são apenas para referência. Consulte o rótulo do produto para obter informações sobre a utilização aplicável. / Următoarele defini ii au numai rol de informare. Consulta i eticheta produsului pentru utilizarea adecvată. / Следующие определения представлены исключительно в ознакомительных целях. Информацию о случаях применения смотрите в инструкции по применению. / Nasledujúce definície slúžia len ako referencie. Príslušné použitie si prečítajte na označení výrobku. / Naslednje definicije so samo informativne narave. Ustrezna uporaba je navedena na etiketi izdelka. / Дефиниције које следе служе само као референце. Прочитајте ознаку на производу за примену производа. / Följande förklaringar är endast för referens. Se produktetikett för lämplig användning. / Aşağıdaki tanımlar sadece başvuru amaçlıdır. İlgili kullanım şekli için lütfen ürün etiketine başvurunuz. / 以下定义仅供参考。有关适用的用途，请参阅产品标签。 / 下列定義僅供參考。請參看產品標籤以瞭解適當的用法。

Caution / Внимание / Upozorn ní / Forsigtig / Achtung / Προσοχή / Precaución / Ettevaatust! / Huomautus / Attention / Oprez / Figyelem / Perhatian / Attenzione / 주의 / Atsargiai / Uzmanību! / Οπομένα / Let op / Forsiktig / Przestroga / Atenção / Aten ie / Внимание / Upozornenie / Previdno / Опрез / Försiktighet / Dikkat / 注意 / 小心

Refer to accompanying Instructions for Use / Консултирайте се с указанията за употреба / Viz přiložený návod k použití / Se medfølgende brugervejledning / Siehe zugehörige Gebrauchsanleitung / Ανατρέξτε στις συνοδευτικές οδηγίες χρήσης / Consulte las Instrucciones de uso adjuntas / Tutvuge kaasasoleva kasutusjuhendiga / Katso käyttöohjeita / Consultez le mode d'emploi joint / Pogledajte priložene upute za uporabu / Használja útmutatóul a mellékelt Használati utasítást / Lihat instruksi penggunaan yang terlampir / Fare riferimento alle Istruzioni per l'uso allegate / 동봉한 사용 설명서를 참조하십시오 / Žr. pridedamą Naudojimo instrukciją / Iepazīstieties ar pievienotajiem lietošanas norādījumiem / Осврнете се на придружното упатство за употреба / Raadpleeg de bijbehorende gebruiksaanwijzing / Se medfølgende bruksinstruksjoner / Sprawdzić w załączonej Instrukcji stosowania / Consultar as Instruções para Utilização inclusas / Consulta i Instruc iunile de utilizare care înso esc produsul / См. Инструкцию по применению, входящую в комплект поставки / Odkazujeme na sprievodný Návod na použitie / Upoštevajte priložena navodila za uporabo / Погледајте приложена упутства за употребу / Se medföljande bruksanvisning / Beraberindeki Kullanma Talimatı'na bakınız / **请参阅随附的使用说明** / 請參閱隨附的使用說明

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Keep Away from Sunlight / Да се пази от слънчева светлина / Chraňte před slunečním sv tlem / Må ikke udsættes for direkte sollys / Vor Sonneneinstrahlung geschützt aufbewahren / Κρατήστε τον μακριά από το φως του ήλιου / Manténgase protegido de la luz solar / Vältige otsest päikesevalgust / Säilytettävä auringonvalolta suojattuna / Conserver à l'abri des rayons du soleil / Držite podalje od sunčeve svjetlosti / Tartsa napfénytől távol / Jauhkan Dari Sinar Matahari / Tenere lontano dalla luce del sole / 직사광선을 피하십시오 / Saugokite nuo saulės šviesos / Sargāt no saules gaismas / Да се чува подалеку од сончева светлина / Beschermen tegen zonlicht / Hold bort fra sollys / Chronić przed światłem słonecznym / Manter afastado da luz solar / Feri i de lumina soarelui / Беречь от действия солнечного света / Chráňte pred priamym slnečným svetlom / Ne hranite na sončni svetlobi / Не излагати сунчевој светлости / Skyddas från solljus / Güneş ışığından koruyunuz / 避光 / 遠離陽光照射

Keep Dry / Да се съхранява на сухо място / Uchovávejte v suchu / Opbevares tørt / Trocken aufbewahren / Διατηρήστε τον στεγνό / Mantener seco / Hoida kuivana / Säilytettävä kuivassa / Garder au sec / Proizvod održavajte suhim / Tartsa szárazon / Jagalah Agar Tetap Kering / Mantenere all'asciutto / 건조 유지 / Laikykite sausoje vietoje / Turēt sausu / Да се чува на суво место / Droog houden / Oppbevares tørt / Chronić przed wilgocią / Manter seco / A se păstra uscat / Хранить в сухом месте / Uchovávajte v suchu / Hranite na suhem / Чувати на сувом месту / Förvaras torrt / Kuru tutunuz / 持干燥 / 保持乾燥

Serial Number / Сериен номер / Sériové číslo / Serienummer / Seriennummer / Σειριακός αριθμός / Número de serie / Seerianumber / Sarjanumero / Numéro de série / Serijski broj / Sorozatszám / Nomor Seri / Numero di serie / 일련번호 / Serijos numeris / Sērijas numurs / Сериски број / Serienummer / Serienummer / Numer seryjny / Número de série / Număr de serie / Серийный номер / Výrobné číslo / Serijska številka / Серијски број / Serienummer / Seri Numarası / **序列号** / 序號

Catalog Number / Каталожен номер / Katalogové číslo / Katalognummer / Katalognummer / Αριθμός καταλόγ υ / N.º de catálogo / Kataloogi number / Tuotenumero / Numéro de référence / Kataloški broj / Katalógusszám / Nomor katalog / Numero di catalogo / 카탈로그 번호 / Katalogo numeris / Numurs katalogā / Каталошки број / Bestelnummer / Katalognummer / Numer katalogowy / Número do catálogo / Număr de catalog / Каталожный номер / Kód výrobku / Kataloška številka / Каталошки број / Katalognummer / Katalog numarası / 目录编号 / 目錄號

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Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Valmistaja / Fabricant / Proizvođač / Gyártó / Produsen / Produttore / 제조업체 / Gamintojas / Ražotājs / Производител / Fabrikant / Produsent / Producent / Fabricante / Producător / Производитель / Výrobca / Izdelovalec / Произвођач / Tillverkare / Üretici / 制造商 / 製造商

EC REP

Authorized Representative in the European Community / Упълномощен представител в Европейския съюз / Oprávn ný zástupce v Evropských společenstvích / Godkendt repræsentant i EU / Bevollmächtigter in der Europäischen Gemeinschaft / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Ένωση / Representante autorizado en la Comunidad Europea / Volitatud esindaja Euroopa Ühenduses / Valtuutettu edustaja Euroopan yhteisössä / Mandataire européen / Ovlašteni predstavnik u Europskoj zajednici / Hivatalos képviselet az Európai Közösségben / Perwakilan Resmi Komunitas Eropa / Rappresentante autorizzato nella Comunità Europea / European Community 공식 판매점 / Įgaliotasis atstovas Europos Bendrijoje / Pilnvarotais pārstāvis Eiropas Kopienā / Овластен претставник во Европската заедница / Geautoriseerd vertegenwoordiger in de Europese Gemeenschap / Autorisert EU-representant / Autoryzowany przedstawiciel we Wspólnocie Europejskiej / Representante autorizado na Comunidade Europeia / Reprezentant autorizat în Comunitatea Europeană / Официальное представительство в Европейском Сообществе / Oprávnený zástupca v Európskom spoločenstve / Pooblaščeni predstavnik za Evropsko skupnost / Овлашћени представник за Европску заједницу / Auktoriserad representant inom den Europeiska gemenskapen / Avrupa Topluluğundaki Yetkili Temsilci / 欧盟授权代表 / 歐洲共同體授權代表

Date of Manufacture / Дата на производство / Datum výroby / Fremstillingsdato / Herstellungsdatum / Ημερ μηνία κατασκευής / Fecha de fabricación / Tootmiskuupäev / Valmistuspäivä / Date de fabrication / Datum proizvodnje / Gyártás dátuma / Tanggal Produksi / Data di fabbricazione / 제조일자 / Pagaminimo data / Izgatavošanas datums / Датум на производство / Productiedatum / Produksjonsdato / Data produkcji / Data de fabrico / Data fabrica iei / Дата изготовления / Dátum výroby / Datum izdelave / Датум производње / Tillverkningsdatum / Üretim Tarihi / 制造日期 / 製造日期

Pin Connector / Пин конектор / Kolíkový konektor / Hanstik / Stiftverbinder / Συνδετικό ακίδων / Conector de terminales / Pistikühendus / Nastaliitin / Connecteur à broche / Iglični priključnik / Tűs csatlakozódugó / Konektor Pin / Connettore a pin / 핀 커넥터 / Šakučių jungtis / Kontaktu savienotājs / Приклучок со иглички / Pinconnector / Hann-nålekontakt / Złącze pinowe / Conector de pinos / Conector cu pini / Штекерный разъем / Pinový konektor / Vtični konektor / Иглични прикључак / Stiftkontakt / Pin Konektörü / 针连接器 / 針連接器

Temperature Limit / Температурно ограничение / Teplotní limit / Temperaturgrænse / Temperaturgrenze / Όριο θερμοκρασίας / Límite de temperatura / Temperatuuri piirnorm / Lämpötilaraja / Limite de température / Ograničenje temperature / Hőmérsékleti határérték / Batasan Suhu / Limite di temperatura / 온도 한도 / Temperatūros ribos / Temperatūras ierobežojums / Ограничување на температурата / Temperatuurlimiet / Temperaturgrense / Limit temperatury / Limite de temperatura / Limită de temperatură / Предельно допустимая температура / Teplotný rozsah / Temperaturna omejitev / Температурно ограничење / Temperaturgräns / Sıcaklık Limiti / 温度限值 / 溫度限制

Rx only

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Separate collection for electrical and electronic equipment, in compliance with Waste Electrical and Electronic Equipment Directive (WEEE) / Разделно събиране на електрическо и електронно оборудване, в съответствие с Директивата за отпадъци от електрическо и електронно оборудване (OEEO) / Samostatný sb r elektrického a elektronického zařízení v souladu se sm rnicí o odpadních elektrických a elektronických zařízeních (OEEZ) / Separat indsamling af elektrisk og elektronisk udstyr I overensstemmelse med direktivet om affald af elektrisk og elektronisk udstyr (WEEE) / Getrennte Sammlung von Elektro- und Elektronikgeräten gemäß Richtlinie über Elektro- und Elektronik-Altgeräte (WEEE) / Η αποκομιδή του ηλεκτρικού και ηλεκτρονικού εξοπλισμού πρέπει να γίνεται ξεχωριστά, σε συμμόρφωση με την Οδηγία σχετικά με τα απόβλητα ηλεκτρικού και ηλεκτρονικού εξοπλισμού (WEEE) / Recogida selectiva de equipos eléctricos y electrónicos, de conformidad con la directiva sobre residuos de aparatos eléctricos y electrónicos (RAEE) / Elektriliste ja elektrooniliste seadmete eraldi kogumine, lähtudes elektrija elektroonikaseadmete jäätmete direktiivist (WEEE) / Erillinen sähkö- ja elektroniikkalaitteiden keräys sähkö- ja elektroniikkalaiteromudirektiivin (WEEE) mukaisesti / Dispositifs électriques et électroniques devant être collectés séparément, conformément à la directive relative aux déchets d'équipements électriques et électroniques (DEEE) / Odvojeno sakupljanje električne i elektroničke opreme, u skladu s Direktivom o otpadnoj električnoj i elektroničkoj opremi (OEEO) / Az elektromos és elektronikus berendezések hulladékairól szóló (WEEE) irányelvnek eleget tevő szelektív hulladékgyűjtés / Pisahkan pengumpulan peralatan elektrik dan elektronik, menurut Petunjuk Limbah Peralatan Listrik dan Elektronik (Waste Electrical and Electronic Equipment Directive, WEEE) / Raccolta differenziata per apparecchiature elettriche o elettroniche, in conformità con la direttiva in materia di rifiuti di apparecchiature elettriche ed elettroniche (RAEE) / 폐전기 전자 장비 지침(WEEE)에 따라 전기 전자 장비를 분리 수거하십시오 / Elektros ir elektroninė įranga turi būti utilizuojama atskirtai, kaip nurodyta elektros ir elektroninės įrangos atliekų direktyvoje (EEĮA) / Atsevišķa elektriskā un elektroniskā aprīkojuma savākšana atbilstoši direktīvai par Elektrisko un elektronisko iekārtu atkritumiem (EEIA) / Одделно собирање отпад за електрична и електронска опрема, во согласност со Директивата за отпадна електрична и електронска опрема (WEEE) / Gescheiden inzameling van elektrische en elektronische apparatuur, in navolging van de richtlijn voor Afgedankte Elektrische en Elektronische Apparatuur (AEEA) / Separat innsamling for elektrisk og elektronisk utstyr i samsvar med WEEE (Waste Electrical and Electronic Equipment Directive) / Osobne składowanie sprz tu elektrycznego i elektronicznego zgodnie z dyrektywą w sprawie zużytego sprz tu elektrycznego i elektronicznego (WEEE) / Recolha separada de equipamentos elétricos e eletrónicos, em conformidade com a Diretiva de Resíduos de Equipamentos Elétricos e Eletrónicos (REEE) / Colectarea separată pentru echipamentele electrice și electronice, în conformitate cu directiva WEEE (recuperarea deșeurilor de echipamente electrice și electronice) / Раздельный сбор на утилизацию электрического и электронного оборудования в соответствии с Директивой об отработавшем электрическом и электронном оборудовании (WEEE) / Separovaný zber elektrického a elektronického zariadenia v súlade so smernicou o odpade z elektrických a elektronických zariadení (OEEZ) / Ločeno zbiranje za električno in elektronsko opremo v skladu z Direktivo o odpadni električni in elektronski opremi (OEEO) / Одвојено сакупљање електричног и електронског отпада у складу са Директивом о електричном и електронском отпаду (WEEE) / Separat insamling av elektrisk och elektronisk utrustning i enlighet med direktivet om avfall som utgörs av eller innehåller elektriska eller elektroniska produkter (WEEE) / Atık Elektrikli ve Elektronik Ekipman Direktifi (WEEE) uyarınca elektrikli ve elektronik ekipman için ayrı toplama / 按照《废弃电气和电子设备指令》(WEEE) 分类收集电气和电子设备 / 請依照歐盟廢電子電機設備指令 (WEEE) 單獨收集電氣及電子設備

# TX *eco* Cable

**Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.**

- Do not use if the package is opened or damaged.

## DEVICE DESCRIPTION

The TX *eco* Cable is used with an extension cable to connect a Biosense Webster therapeutic catheter to the Patient Interface Unit (PIU) of the CARTO™ 3 System (Version 6 and later). The extension cables are listed below:

- For the QDOT™ Micro Catheter: TX *eco* EXT Cable D135703
- For other Biosense Webster therapeutic catheters: D128603 (catalog # CR3434CT) or D128604 (catalog # CR3425CT)

The TX *eco* Cable communicates data from a Biosense Webster therapeutic catheter to the CARTO™ 3 System and the RF generator. The information communicated is listed below.

- Force signals
- Location signals
- IC signals from the 3 microelectrodes in the tip of the catheter (for catheters with microelectrodes only)
- Temperature measurements from the 6 thermocouples in the tip of the catheter

## INDICATIONS FOR USE

The TX *eco* Cable is used to connect a Biosense Webster therapeutic catheter to the Patient Interface Unit (PIU) of the CARTO™ 3 System (Version 6 and later).

## WARNINGS

1. Before using this cable, read the *Instructions for Use* for the Biosense Webster therapeutic catheter. If this cable is being used with the QDOT MICRO™ Module, refer to the *Instructions for Use* for the CARTO™ 3 System and the *Instructions for Use and Release Notes* for the QDOT MICRO™ Module before using this cable with the QDOT MICRO™ Module.
2. Only personnel who have read and understood the contents of this document may set up and use this cable.
3. This cable is only validated for use with a Biosense Webster therapeutic catheter. Do not connect this cable to any other catheter.
4. This cable is intended for use only with a Biosense Webster therapeutic catheter, a compatible RF generator, a CARTO™ 3 System, and Biosense Webster cables. Consult your Biosense Webster representative for details.
5. This cable must be at least 1 meter (39.4 in) away from the location pad of the CARTO™ 3 System during the procedure.
6. This cable must be connected to the PIU of the CARTO™ 3 System for a 5-minute warm-up period before use to ensure accurate temperature readings. After the warm-up period, the temperature readings stabilize. If the cable is used before the end of the warm-up period, a temperature drift might occur.

## INSTALLING AND OPERATING THE CABLE

### Attaching the Cable Holder

1. Place the clamp portion of the cable holder (part number M652802) on the side of the CARTO™ System Cart handle or over the bed rail. Then tighten the knob on the cable holder.
2. Insert the cable in the cable holder with the cable facing down.

### Connecting the Cable

1. Connect the cable's red connector to the MAP socket on the PIU of the CARTO™ 3 System.
2. Connect the cable's yellow connector to the QUAD B or DECA socket on the PIU.

   Note 1: Both connectors must be connected to the PIU.

   Note 2: Connecting the connector to QUAD A may result in undesirable ECG noise.
3. If using a QDOT™ Micro Catheter, connect the catheter to one end of the TX *eco* EXT Cable. Connect the other end of the TX *eco* EXT Cable to the large socket at the end of the TX *eco* Cable.
4. If using another Biosense Webster therapeutic catheter, connect the catheter to one end of the extension cable. Connect the other end of the extension cable to the small round socket at the end of the TX *eco* Cable.

### Disconnecting the Cable

1. Disconnect the red connector from the PIU of the CARTO™ 3 System by pulling the connector from the slide release grip.
2. Then disconnect the yellow connector from the PIU by pulling the connector from the slide release grip.

   Note: Both connectors must be disconnected from the PIU. Do not leave one cable connected and the other disconnected.
3. After disconnecting the cable, wait 10 seconds before reconnecting the cable to the PIU.

### LED Status

The status of the cable is indicated by an LED. After the cable is properly connected to the PIU of the CARTO™ 3 System and to the Biosense Webster therapeutic catheter, the cable performs a Built-In Test (BIT).

| LED | Cable Status | Comments |
|---|---|---|
| Green: slow blink | BIT in progress | --- |
| Green: solid | Ready for use | --- |
| Red: fast blink | Error, BIT failed | The temperatures are not sent to the CARTO™ 3 System or RF generator. See the *Troubleshooting* section in this document. |

## CARING FOR THE CABLE

### Cleaning

The cable does not require disinfection or sterilization. Do not steam, autoclave, or otherwise sterilize the cable.

If dust or debris appears on the cable, clean the cable as follows:

1. Disconnect the cable.
2. Clean the outside of the cable by wiping it with a cloth dampened with alcohol-free hand soap and water.
3. Ensure that none of the soap solution enters the cable connectors or sockets.
4. Ensure that the cable is dry before connecting it to the CARTO™ 3 System or to a catheter.

### Maintenance

There are no parts in the cable that may be serviced by the user. If the cable fails to perform, contact Customer Support or your Biosense Webster representative for a replacement. The expected useful life of the cable is three years.

### Disposal

Recycle components, or dispose of the product and its residual elements or waste items, in accordance with local laws and regulations.

## TECHNICAL DATA

### Specifications

| | |
|---|---|
| **DC Input** | The cable receives power input from the PIU of the CARTO™ 3 System. |
| **Weight** | 1 kg (2.2 lb) |
| **Dimensions** | 10 in long x 1.9 in wide x 3 in high (254 mm x 48 mm x 76 mm) |
| **Temperature Accuracy** | ≤ 2 °C |

### Operating, Storage, and Shipping Specifications

| | Minimum | Maximum |
|---|---|---|
| **Operating Specifications** | | |
| Ambient Temperature | 10°C | 30°C |
| Relative humidity* | 25% | 75% |
| **Storage and Shipping Specifications** | | |
| Ambient Temperature | -30°C | 65°C |
| Relative humidity* | 10% | 95% |

* In accordance with MIL-STD-1695, relative humidity levels shall be within the range of 30% to 70% in areas where electronic parts and hybrid microcircuits are handled or processed. MIL-STD-1695 requires the same level of relative humidity controls for handling and storage areas, except when items are covered or protected.

### EMC Information

The TX *eco* Cable is intended for use in the electromagnetic environment as specified in the *Instruction for Use* for the CARTO™ 3 System.

## TROUBLESHOOTING

If the LED on the TX *eco* Cable is red and is blinking fast, the BIT has failed and has caused an error (see the *LED Status* section in this document). Follow the steps below to correct the problem.

1. Disconnect the catheter from the cable.
2. Disconnect the cable from the PIU of the CARTO™ 3 System.
3. Reconnect the cable to the PIU.
4. Reconnect the catheter to the cable.
5. If a QDOT MICRO™ Module is being used, follow the directions in the *Instructions for Use and Release Notes* for the QDOT MICRO™ Module.
6. If the problem persists, contact Customer Support or your Biosense Webster representative.

In some situations, where 15 kV of air discharge or 8 kV of contact discharge is applied on the system, the CARTO™ 3 System displays 3 error messages simultaneously: Map points cannot be acquired (Error 401), Patient Body Reference has moved (Error 256), and a popup message indicating the Patient Body Reference change. If this occurs, restart the PIU.

## DISCLAIMER OF WARRANTY AND LIMITATION OF LIABILITY

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Descriptions and specifications appearing in Biosense Webster, Inc. printed matter, including this publication, are informational only and meant solely to generally describe the product(s) at the time of manufacture and are not made or given as a warranty of the prescribed product(s) in any way.

## ELECTRONIC INSTRUCTIONS FOR USE

This document is available at www.e-ifu.com.

# TX *eco* кабел

**Внимание: Федералните закони (на САЩ) ограничават продажбата на това изделие от или по поръчка на лицензиран здравен професионалист.**

- Да не се използва, ако опаковката е отворена или повредена.

## ОПИСАНИЕ НА ИЗДЕЛИЕТО

TX *eco* кабелът се използва с удължителен кабел, за да свърже терапевтичен катетър на Biosense Webster към пациентския интерфейсен модул (PIU) на системата CARTO™ 3 (версия 6 или по-нова версия). Удължителните кабели са изброени по-долу:

- За микрокатетър QDOT™: TX *eco* EXT кабел D135703
- За други терапевтични катетри Biosense Webster: D128603 (каталожен номер CR3434CT) или D128604 (каталожен номер CR3425CT)

TX *eco* кабелът предава данни от терапевтичния катетър на Biosense Webster към системата CARTO™ 3 и РЧ генератор. Предадената информация е описана по-долу.

- Сигнали за сила
- Сигнали за местоположение
- IC сигнали от 3 микроелектрода на върха на катетъра (само за катетри с микроелектроди)
- Измервания на температурата от 6 термодвойки на върха на катетъра

## ПОКАЗАНИЯ ЗА УПОТРЕБА

TX *eco* кабелът се използва, за да свърже терапевтичен катетър на Biosense Webster към пациентския интерфейсен модул (PIU) на системата CARTO™ 3 (версия 6 или по-нова).

## ПРЕДУПРЕЖДЕНИЯ

1. Преди да използвате този кабел, прочетете *инструкциите за употреба* за терапевтичния катетър на Biosense Webster. Ако този кабел се използва с модула QDOT MICRO™, направете справка с *инструкциите за употреба* за системата CARTO™ 3 и *инструкциите за употреба и бележките за изданието* за модула QDOT MICRO™, преди да използвате този кабел с модула QDOT MICRO™.
2. Само персонал, който е прочел и разбрал съдържание на този документ, може да настрои и използва този кабел.
3. Този кабел е утвърден за употреба само с терапевтичен катетър на Biosense Webster. Не свързвайте този кабел към никакъв друг катетър.
4. Този кабел е предназначен за употреба единствено с терапевтичен катетър на Biosense Webster, съвместим РЧ генератор, системата CARTO™ 3 и кабели на Biosense Webster. Обърнете се към Вашия представител на Biosense Webster за подробна информация.
5. Този кабел трябва да е отдалечен на поне 1 метър (39,4 инча) от подложката за местоположение на системата CARTO™ 3 по време на процедурата.
6. Този кабел трябва да е свързан към пациентския интерфейсен модул (PIU) на системата CARTO™ 3 за 5-минутен период на подгряване преди употреба, за да се гарантират точни отчитания на температурата. След периода на подгряване отчитания на температурата се стабилизират. Ако кабелът се използва преди края на периода на подгряване, може да се появи температурен дрейф.

## МОНТАЖ И РАБОТА С КАБЕЛА

### Прикачване на държача за кабела

1. Поставете частта със скобата на държача за кабела (каталожен номер M652802) на страната на дръжката на количката на системата CARTO™ или над преградата на леглото. След това затегнете копчето на държача за кабела.
2. Пъхнете кабела в държача за кабела, като кабелът да сочи надолу.

### Свързване на кабела

1. Свържете червения конектор на кабела към гнездото MAP на пациентския интерфейсен модул (PIU) на системата CARTO™ 3.
2. Свържете жълтия конектор на кабела към гнездото QUAD B или DECA на пациентския интерфейсен модул (PIU).

   Забележка 1: Двата конектора трябва да бъдат свързани към пациентския интерфейсен модул (PIU).

   Забележка 2: Свързването на конектора към QUAD A може да доведе до нежелан шум в ЕКГ.
3. Ако използвате микрокатетър QDOT™, свържете катетъра към единия край на TX *eco* EXT кабела. Свържете другия край на TX *eco* EXT кабела към голямото гнездо в края на TX *eco* кабела.
4. Ако използвате друг терапевтичен катетър на Biosense Webster, свържете катетъра към единия край на удължителния кабел. Свържете другия край на удължителния кабел към малкото, кръгло гнездо в края на TX *eco* кабела.

### Прекъсване на връзката на кабела

1. Прекъснете връзката на червения конектор от пациентския интерфейсен модул (PIU) на системата CARTO™ 3, като издърпате конектора от плъзгащия се захват.
2. След това прекъснете връзката на жълтия конектор от пациентския интерфейсен модул (PIU), като издърпате конектора от плъзгащия се захват.

   Забележка: Връзките на двата конектора с пациентския интерфейсен модул (PIU) трябва да бъдат прекъснати. Не оставяйте един кабел свързан, а другия – разкачен.
3. След прекъсване на връзката на кабела изчакайте 10 секунди, преди да свържете отново кабела към пациентския интерфейсен модул (PIU).

### Светодиоден статус

Статусът на кабела е посочен чрез светодиод. След като кабелът е правилно свързан към пациентския интерфейсен модул (PIU) на системата CARTO™ 3 и терапевтичния катетър на Biosense Webster, кабелът извършва вграден тест (BIT).

| Светодиод | Статус на кабела | Коментари |
|---|---|---|
| Зелен: мига бавно | Извършва се вграден тест (BIT) | --- |
| Зелен: свети | Готов за употреба | --- |
| Червен: мига бързо | Грешка, неуспешен вграден тест (BIT) | Температурите не се изпращат към системата CARTO™ 3 или РЧ генератора.<br>Вижте раздела *Отстраняване на неизправности* в този документ. |

## ГРИЖИ ЗА КАБЕЛА

### Почистване

Кабелът не изисква дезинфекция или стерилизация. Не стерилизирайте кабела с пара, в автоклав или по друг начин.

Ако върху кабела се събере прах или мръсотия, почистете кабел по следния начин:

1. Прекъснете връзката на кабела.
2. Почистете кабела отвън, като го изтриете с кърпа, навлажнена с безалкохолен сапун и вода.
3. Уверете се, че в кабелните конектори или гнезда не прониква сапунен разтвор.
4. Уверете се, че кабелът е сух, преди да го свържете към системата CARTO™ 3 или катетъра.

### Поддръжка

В кабела няма части, които могат да бъдат обслужвани от потребителя. Ако кабелът не функционира, обърнете се към екипа за клиентска поддръжка или вашия представител на Biosense Webster за смяна на кабела. Очакваният полезен живот на кабела е три години.

### Изхвърляне

Рециклирайте компонентите или изхвърляйте продукта и остатъчните му елементи или отпадъчни елементи в съответствие с местните закони и разпоредби.

## ТЕХНИЧЕСКИ ДАННИ

### Спецификации

| | |
|---|---|
| **Променливотоков вход** | Кабелът получава захранване от пациентския интерфейсен модул (PIU) на системата CARTO™ 3. |
| **Тегло** | 1 kg (2,2 фунта) |
| **Размери** | 10 инча x 1,9 инча x 3 инча<br>(254 mm x 48 mm x 76 mm) |
| **Точност на температурата** | ≤ 2 °C |

### Спецификации за работа, съхранение и транспортиране

| | Минимум | Максимум |
|---|---|---|
| **Работни спецификации** | | |
| Околна температура | 10 °C | 30 °C |
| Относителна влажност* | 25% | 75% |
| **Спецификации за съхранение и транспортиране** | | |
| Околна температура | -30 °C | 65 °C |
| Относителна влажност* | 10% | 95% |

* Съгласно MIL-STD-1695 нивата на относителна влажност трябва да бъдат в диапазона от 30% до 70% в области, където се обработват или преработват електронни части и хибридни микрочипове. MIL-STD-1695 изисква същото ниво на контроли на относителна влажност за области за обработване и съхранение с изключение на случая, когато елементите са покрити или защитени.

### Информация

TX *eco* кабелът е предназначен за употреба в електромагнитна среда, както е указано в *указанията за употреба* за системата CARTO™ 3.

## ОТСТРАНЯВАНЕ НА НЕИЗПРАВНОСТИ

Ако светодиодът на TX *eco* кабела е червен и мига бързо, вграденият тест (BIT) е неуспешен и е предизвикал грешка (вижте раздел *Светодиоден статус* в този документ). Следвайте стъпките по-долу, за да отстраните проблема.

1. Прекъснете връзката на катетъра и кабела.
2. Прекъснете връзката на кабела с пациентския интерфейсен модул (PIU) на системата CARTO™ 3.
3. Свържете отново кабела към пациентския интерфейсен модул (PIU).
4. Свържете отново катетъра към кабела.
5. Ако се използва модул QDOT MICRO™, следвайте *инструкциите в указанията за употреба и бележките по изданието* за модула QDOT MICRO™.
6. Ако проблемът не изчезне, се обърнете към екипа за клиентска поддръжка или Вашия представител на Biosense Webster.

В някои случаи, когато на системата се прилагат 15 kV въздушен разряд или 8 kV контактен разряд, системата CARTO™ 3 показва едновременно три съобщения за грешка: не могат да бъдат определени картографските точки (грешка 401), референтната позиция на тялото на пациента се е преместила (грешка 256) и изскачащ прозорец, показващ промяната на референтната позиция на тялото на пациента. Ако това се случи, рестартирайте пациентския интерфейсен модул (PIU).

## ГАРАНЦИЯ И ОГРАНИЧЕНА ОТГОВОРНОСТ

**ЗА ТУК ОПИСАНИЯ(ТЕ) ПРОДУКТ(И) НЯМА ДИРЕКТНА ИЛИ ПОДРАЗБИРАЩА СЕ ГАРАНЦИЯ, ВКЛЮЧИТЕЛНО, БЕЗ ОГРАНИЧЕНИЯ, КАКВАТО И ДА БИЛО ПРЕДПОЛАГАЕМА ГАРАНЦИЯ ЗА ТЪРГОВСКА РЕАЛИЗАЦИЯ ИЛИ ПРИГОДНОСТ ЗА ОПРЕДЕЛЕНА ЦЕЛ. ПРИ НИКАКВИ ОБСТОЯТЕЛСТВА BIOSENSE WEBSTER, INC. ИЛИ СВЪРЗАНИТЕ С ТЯХ КОМПАНИИ, НЯМА ДА НОСЯТ ОТГОВОРНОСТ ЗА КАКВИТО И ДА СА ОСОБЕНИ, ПРЕКИ, СЛУЧАЙНИ, ПОСЛЕДВАЩИ ИЛИ ДРУГИ УВРЕДИ, ОСВЕН ИЗРИЧНО ПОСОЧЕНИТЕ ОТ ПРИЛОЖНОТО ЗАКОНОДАТЕЛСТВО.**

**БЕЗ ДА ОГРАНИЧАВА ГОРЕПОСОЧЕНОТО, BIOSENSE WEBSTER, INC. ИЛИ ТЕХНИТЕ СВЪРЗАНИ КОМПАНИИ, НЯМА ДА БЪДАТ ОТГОВОРНИ ЗА КАКВИТО И ДА БИЛО ОСОБЕНИ, ПРЕКИ, ИНЦИДЕНТНИ, КОСВЕНИ ИЛИ ДРУГИ ВРЕДИ, ВЪЗНИКНАЛИ ВСЛЕДСТВИЕ НА ПОВТОРНА УПОТРЕБА НА ПРОДУКТ(И), ОБОЗНАЧЕН(И) ЗА ЕДНОКРАТНА УПОТРЕБА, ИЛИ КЪДЕТО ПОВТОРНАТА УПОТРЕБА Е ЗАБРАНЕНА ОТ СЪОТВЕТНОТО ЗАКОНОДАТЕЛСТВО.**

Описания и спецификации, срещащи се в печатни материали на Biosense Webster, Inc., включително в тази публикация, са само за информация и целят единствено да представят общо описание на продукта към момента на производство, и по никакъв начин не са предназначени или предоставени като гаранция на дадения продукт.

## ЕЛЕКТРОННИ ИНСТРУКЦИИ ЗА УПОТРЕБА

Този документ е наличен на www.e-ifu.com.

# Kabel TX *eco*

**Upozorn ní: Federální zákony USA omezují prodej tohoto zařízení na prodej lékařem s licencí nebo na lékařský předpis.**

- Produkt nepoužívejte, pokud je obal otevřený nebo poškozený.

## POPIS PROSTŘEDKU

Kabel TX *eco* se používá s prodlužovacím kabelem pro připojení terapeutického katétru Biosense Webster k jednotce zajišťující rozhraní pacienta (PIU) systému CARTO™ 3 (verze 6 a pozd jší). Prodlužovací kabely jsou uvedeny níže:

- Pro mikrokatétr QDOT™: kabel TX *eco* EXT D135703
- Pro další terapeutické katétry Biosense Webster: D128603 (katalogové číslo CR3434CT) nebo D128604 (katalogové číslo CR3425CT)

Kabel TX *eco* zasílá data z terapeutického katétru Biosense Webster do systému CARTO™ 3 a RF generátoru. Zasílané informace jsou uvedeny níže.

- Silové signály
- Signály s informací o poloze
- Intrakardiální signály ze 3 mikroelektrod v hrotu katétru (jen u katétrů s mikroelektrodami)
- M ř ení teploty ze 6 termočlánků v hrotu katétru

## INDIKACE K POUŽITÍ

Kabel TX *eco* se používá k připojení terapeutického katétru Biosense Webster k jednotce zajišťující rozhraní pacienta (PIU) systému CARTO™ 3 (verze 6 a pozd jší).

## VÝSTRAHY

1. Před použitím tohoto kabelu si přečt te *návod k použití* terapeutického katétru Biosense Webster. Jestliže se tento kabel používá s modulem QDOT MICRO™, přečt te si před použitím tohoto kabelu s modulem QDOT MICRO™ *návod k použití* systému CARTO™ 3 a *návod k použití a poznámky k vydání* modulu QDOT MICRO™.
2. Tento kabel smí používat jen osoby, které si přečetly obsah tohoto dokumentu a rozumí mu.
3. Tento kabel je ov ř en jen pro použití s terapeutickým katétrem Biosense Webster. Tento kabel nepřipojujte k žádnému jinému katétru.
4. Tento kabel je určen k použití pouze s terapeutickým katétrem Biosense Webster, kompatibilním RF generátorem, systémem CARTO™ 3 a kabely Biosense Webster. Podrobnosti zjistíte u místního zástupce společnosti Biosense Webster.
5. Tento kabel musí být b hem výkonu ve vzdálenosti minimáln 1 metr (39,4 in) od lokalizační podložky systému CARTO™ 3.
6. Aby bylo zajišt no správné m ř ení teplot, musí být tento kabel b hem 5minutového ohřevu před použitím připojen k jednotce PIU systému CARTO™ 3. Po dob ohřevu se nam ř ené hodnoty teplot ustálí. Bude-li kabel použit před koncem doby ohřevu, může dojít ke kolísání teploty.

## INSTALACE A POUŽÍVÁNÍ KABELU

### Připevn ní držáku kabelu

1. Část držáku kabelu (díl číslo M652802) se svorkou umíst te na bok rukojeti vozíku k systému CARTO™ nebo nad madlo postele. Pak utáhn te kolečko na držáku kabelu.
2. Vložte kabel do držáku kabelu tak, aby kabel sm ř oval dolů.

### Připojení kabelu

1. Červený konektor kabelu zapojte do zdířky MAP na jednotce PIU systému CARTO™ 3.
2. Žlutý konektor kabelu zapojte do zdířky QUAD B nebo DECA na jednotce PIU.

   Poznámka 1: Oba konektory musí být zapojené do jednotky PIU.

   Poznámka 2: Po zapojení konektoru do zdířky QUAD A může dojít k nežádoucímu rušení signálu EKG.
3. Pokud používáte mikrokatétr QDOT™, připojte katétr k jednomu konci kabelu TX *eco* EXT. Druhý konec kabelu TX *eco* EXT zapojte do velké zdířky na konci kabelu TX *eco*.
4. Pokud používáte jiný terapeutický katétr Biosense Webster, připojte katétr k jednomu konci prodlužovacího kabelu. Druhý konec prodlužovacího kabelu zapojte do malé kulaté zdířky na konci kabelu TX *eco*.

### Odpojení kabelu

1. Odpojte červený konektor od jednotky PIU systému CARTO™ 3 vytažením konektoru z posuvné pojistky.
2. Pak odpojte žlutý konektor z jednotky PIU jeho vytažením z posuvné pojistky.

   Poznámka: Oba konektory je nutné z jednotky PIU odpojit. Nenechávejte jeden kabel zapojený a druhý odpojený.
3. Po odpojení kabelu počkejte 10 sekund, než jej znovu zapojíte do jednotky PIU.

### Stav kontrolky LED

Stav kabelu udává kontrolka LED. Po správném zapojení kabelu do jednotky PIU systému CARTO™ 3 a k terapeutickému katétru Biosense Webster kabel provede tzv. vestav ný test (BIT).

| Kontrolka LED | Stav kabelu | Komentáře |
|---|---|---|
| Zelená: pomalu bliká | Probíhá BIT | Není k dispozici |
| Zelená: svítí | Připraveno k použití | Není k dispozici |
| Červená: rychle bliká | Chyba, BIT se nezdařil | Do systému CARTO™ 3 ani do RF generátoru se neodesílají údaje o teplotách.<br>Viz část *Řešení potíží* v tomto dokumentu. |

## PÉČE O KABEL

### Čišt ní

Kabel není nutné dezinfikovat ani sterilizovat. Kabel nesterilizujte parou, v autoklávu ani jinak.

Bude-li na kabelu prach nebo špína, očist te jej takto:

1. Odpojte kabel.
2. Vn jší povrch kabelu otřete ut rkou navlhčenou mýdlem na ruce bez alkoholu a vodou.
3. Dbejte na to, aby do konektorů kabelu ani do zdířek nevnikl mýdlový roztok.
4. Než kabel připojíte k systému CARTO™ 3 nebo ke katétru, ujist te se, že je suchý.

### Údržba

Kabel neobsahuje součásti, které by mohl opravit uživatel. Jestliže kabel nefunguje, kontaktujte zákaznickou podporu nebo místního zástupce společnosti Biosense Webster s žádostí o náhradní. Předpokládaná životnost kabelu jsou tři roky.

### Likvidace

Recyklujte komponenty nebo likvidujte produkt a jeho zbytkové části či odpady v souladu s místními zákony a předpisy.

## TECHNICKÉ ÚDAJE

### Specifikace

| | |
|---|---|
| **Stejnosm rné napájení** | Kabel je napájen z jednotky PIU systému CARTO™ 3. |
| **Hmotnost** | 1 kg (2,2 lb) |
| **Rozm ry** | Délka 10 in × šířka 1,9 in × výška 3 in (254 mm × 48 mm × 76 mm) |
| **Přesnost teploty** | ≤ 2 °C |

### Specifikace pro provoz, skladování a přepravu

| | Minimální | Maximální |
|---|---|---|
| **Provozní specifikace** | | |
| Okolní teplota | 10 °C | 30 °C |
| Relativní vlhkost* | 25% | 75% |
| **Specifikace pro skladování a přepravu** | | |
| Okolní teplota | -30 °C | 65 °C |
| Relativní vlhkost* | 10% | 95% |

* Podle normy MIL-STD-1695 se relativní vlhkost musí pohybovat v rozmezí 30% až 70% v místech, kde se manipuluje s elektronickými součástmi a mikroobvody nebo kde se zpracovávají. Norma MIL-STD-1695 požaduje stejný stupeň relativní vlhkosti pro prostory pro manipulaci a skladování, pokud tyto předm ty nejsou zakryty či jinak chrán ny.

### Informace o elektromagnetické kompatibilit (EMC)

Kabel TX *eco* je určen pro použití v elektromagnetickém prostředí, jak je uvedeno v *návodu k použití* systému CARTO™ 3.

## ŘEŠENÍ POTÍŽÍ

Pokud kontrolka LED na kabelu TX *eco* rychle červen bliká, test BIT se nezdařil a došlo k chyb (viz část *Stav kontrolky LED* v tomto dokumentu). Problém odstraňte provedením níže uvedených kroků.

1. Odpojte katétr od kabelu.
2. Odpojte kabel z jednotky PIU systému CARTO™ 3.
3. Znovu připojte kabel k jednotce PIU.
4. Znovu připojte katétr ke kabelu.
5. V případ použití modulu QDOT MICRO™ postupujte podle pokynů v *návodu k použití a poznámkách k vydání* pro modul QDOT MICRO™.
6. Pokud problém přetrvává, kontaktujte zákaznickou podporu nebo zástupce společnosti Biosense Webster.

V n kterých případech, kdy je na systém aplikován vzduchový výboj 15 kV nebo kontaktní výboj 8 kV, zobrazí systém CARTO™ 3 zároveň 3 chybová hlášení: Nelze získat mapové body (401), Referenční bod na t le pacienta se pohnul (Chyba 256) a místní hlášení s oznámením, že došlo ke zm n referenčního bodu na t le pacienta. Nastane-li tato situace, restartujte jednotku PIU.

## ODMÍTNUTÍ ZÁRUK A OMEZENÍ ODPOV DNOSTI

**NA ZDE POPSANÝ VÝROBEK (POPSANÉ VÝROBKY) NEEXISTUJE VÝSLOVNÁ ANI NEVÝSLOVNÁ ZÁRUKA VČETN NEOMEZENÉ ZÁRUKY NA MOŽNOST PRODEJE NEBO VHODNOSTI K URČITÉMU ÚČELU. SPOLEČNOST BIOSENSE WEBSTER, INC., NEBO JEJÍ PŘIDRUŽENÉ SPOLEČNOSTI ZA ŽÁDNÝCH OKOLNOSTÍ NERUČÍ ZA ŽÁDNÉ SPECIÁLNÍ, PŘÍMÉ, NÁHODNÉ, NÁSLEDNÉ NEBO JINÉ ŠKODY S VÝJIMKOU T CH, KTERÉ JSOU UVEDENY V PŘÍSLUŠNÉM ZÁKON .**

**BEZ OMEZENÍ USTANOVENÍ UVEDENÉHO V PŘEDCHÁZEJÍCÍM ODSTAVCI SPOLEČNOST BIOSENSE WEBSTER, INC. NEBO JEJÍ PŘIDRUŽENÉ SPOLEČNOSTI ZA ŽÁDNÝCH OKOLNOSTÍ NERUČÍ ZA ŽÁDNÉ SPECIÁLNÍ, PŘÍMÉ, NÁHODNÉ, NÁSLEDNÉ NEBO JINÉ ŠKODY, KTERÉ VZNIKNOU OPAKOVANÝM POUŽITÍM VÝROBKU (VÝROBKŮ) URČENÝCH POUZE PRO JEDNO POUŽITÍ NEBO V PŘÍPAD , ŽE JE JEJICH OPAKOVANÉ POUŽITÍ ZAKÁZÁNO PŘÍSLUŠNÝM ZÁKONEM.**

Popisy a specifikace objevující se v tišt ných dokumentech společnosti Biosense Webster, Inc. včetn této publikace jsou pouze informativní a uvád jí pouze všeobecný popis výrobku v dob výroby a v žádném případ neposkytují záruku pro popsaný výrobek a nejsou ani takto mín ny.

## ELEKTRONICKÝ NÁVOD K POUŽITÍ

Tento dokument je k dispozici na adrese www.e-ifu.com.

# TX *eco*-kabel

**Forsigtig: Ifølge amerikansk lovgivning (USA) må denne anordning udelukkende sælges af eller efter ordination fra en læge.**

- Må ikke anvendes, hvis emballagen har været åbnet eller er beskadiget.

## BESKRIVELSE AF ANORDNINGEN

TX *eco*-kablet bruges sammen med et forlængerkabel til at forbinde et terapeutisk Biosense Webster-kateter med den anvendte patientgrænsefladeenhed i CARTO™ 3-systemet (version 6 og nyere). Forlængerkablerne er opført nedenfor:

- For QDOT™-mikrokateteret: TX *eco* EXT-kabel D135703
- For andre terapeutiske Biosense Webster-katetre: D128603 (katalognr. CR3434CT) eller D128604 (katalognr. CR3425CT)

TX *eco*-kablet sender data fra et terapeutisk Biosense Webster-kateter til CARTO™ 3-systemet og RF-generatoren. De sendte oplysninger er anført nedenfor.

- Kraftsignaler
- Lokaliseringssignaler
- IC-signaler fra de 3 mikroelektroder på spidsen af kateteret (kun katetre med mikroelektroder)
- Temperaturmålinger fra de 6 termoelementer på spidsen af kateteret

## INDIKATIONER

TX *eco*-kablet bruges til at forbinde et terapeutisk Biosense Webster-kateter med den anvendte patientgrænsefladeenhed i CARTO™ 3-systemet (version 6 og nyere).

## ADVARSLER

1. Læs *brugsanvisningen* til det terapeutiske Biosense Webster-kateter, inden dette kabel tages i brug. Hvis dette kabel bruges sammen med QDOT MICRO™-modulet, henvises der til *brugsanvisningen* til CARTO™ 3-systemet samt *brugsanvisningen og produktbemærkningerne* til QDOT MICRO™-modulet inden dette kabel anvendes sammen med QDOT MICRO™-modulet.
2. Kun personer, som har læst og forstået indholdet af dette dokument, må indstille og bruge dette kabel.
3. Dette kabel er udelukkende valideret til brug med et terapeutisk Biosense Webster-kateter. Dette kabel må ikke forbindes med andre katetre.
4. Dette kabel er kun beregnet til brug sammen med et terapeutisk Biosense Webster-kateter, en kompatibel RF-generator, et CARTO™ 3-system og Biosense Webster-kabler. Yderligere oplysninger fås hos Biosense Webster-repræsentanten.
5. Dette kabel skal være placeret mindst 1 meter (39,4 tommer) fra CARTO™ 3-systemets lokaliseringsenhed under proceduren.
6. Dette kabel skal forbindes med patientgrænsefladeenheden i CARTO™ 3-systemet i en 5 minutters opvarmningsperiode inden brug for at sikre nøjagtige temperaturmålinger. Temperaturmålingerne stabiliserer sig efter opvarmningsperioden. Hvis kablet bruges, inden opvarmningsperioden er udløbet, kan der forekomme en temperaturforskydning.

## INSTALLATION OG BETJENING AF KABLET

### Fastgørelse af kabelholderen

1. Anbring kabelholderens klemmedel (delnummer M652802) på siden af håndtaget på CARTO™-systemets vogn eller over sengeskinnen. Stram derefter grebet på kabelholderen.
2. Indsæt kablet i kabelholderen med kablet vendt nedad.

### Tilslutning af kablet

1. Forbind kablets røde konnektor med MAP-stikket på CARTO™ 3-systemets patientgrænsefladeenhed.
2. Forbind kablets gule konnektor med QUAD B- eller DECA-stikket på patientgrænsefladeenheden.

   Bemærk 1: Begge konnektorer skal være forbundet med systemets patientgrænsefladeenhed.

   Bemærk 2: Hvis konnektoren forbindes med QUAD A-stikket, kan det medføre uønskede EKG-forstyrrelser.
3. Hvis der anvendes et QDOT™-mikrokateter, skal kateteret forbindes med den ene ende af TX *eco* EXT-kablet. Forbind den anden ende af TX *eco* EXT-kablet med det store stik for enden af TX *eco*-kablet.
4. Hvis der anvendes et andet terapeutisk Biosense Webster-kateter, skal kateteret forbindes med den ene ende af forlængerkablet. Forbind den anden ende af forlængerkablet med det lille, runde stik for enden af TX *eco*-kablet.

### Frakobling af kablet

1. Kobl den røde konnektor fra CARTO™ 3-systemets patientgrænsefladeenhed ved at trække konnektoren ud af frigørelsesmekanismen.
2. Kobl derefter den gule konnektor fra patientgrænsefladeenheden ved at trække konnektoren ud af frigørelsesmekanismen.

   Bemærk: Begge konnektorer skal kobles fra patientgrænsefladeenheden. Lad ikke det ene kabel være forbundet og det andet frakoblet.
3. Vent 10 sekunder efter frakobling af kablet, inden kablet forbindes med patientgrænsefladeenheden igen.

### LED-status

En LED viser kablets status. Når kablet er sluttet korrekt til CARTO™ 3-systemets patientgrænsefladeenhed og til det anvendte Biosense Webster terapeutiske kateter, gennemfører kablet en selvtest.

| LED | Kabelstatus | Kommentarer |
|---|---|---|
| Grøn: blinker langsomt | Selvtest i gang | --- |
| Grøn: lyser konstant | Klar til brug | --- |
| Rød: blinker hurtigt | Fejl, mislykket selvtest | Temperaturerne sendes ikke til CARTO™ 3-systemet eller RF-generatoren.<br>Se afsnittet *Fejlfinding* i dette dokument. |

## VEDLIGEHOLDELSE AF KABLET

### Rengøring

Kablet kræver ikke desinfektion eller sterilisering. Kablet må ikke dampsteriliseres, autoklaveres eller steriliseres på anden vis.

I tilfælde af, at der er støv eller snavs på kablet, skal det rengøres på følgende vis:

1. Frakobl kablet.
2. Rengør kablet udvendigt ved at aftørre det med en klud, der er fugtet med alkoholfri håndsæbe og vand.
3. Sørg for, at sæbeopløsningen ikke trænger ind i kabelkonnektorerne og stikkene.
4. Sørg for, at kablet er tørt, inden det forbindes med CARTO™ 3-systemet eller et kateter.

### Vedligeholdelse

Der er ingen dele i kablet, der kan serviceres af brugeren. Hvis kablet ikke fungerer efter hensigten, skal du kontakte kundeservice eller Biosense Webster-repræsentanten med henblik på bestilling af et nyt kabel. Kablets forventede driftslevetid er tre år.

### Bortskaffelse

Genanvend dele, eller bortskaf produktet samt restelementer eller affaldsdele i overensstemmelse med lokal love og regulativer

## TEKNISKE DATA

### Specifikationer

| | |
|---|---|
| **Jævnstrømsindgang** | Kablet forsynes med strøm fra CARTO™ 3-systemets patientgrænsefladeenhed. |
| **Vægt** | 1 kg (2,2 lb) |
| **Mål** | 10 in lang x 1,9 in bred x 3 in høj<br>(254 mm x 48 mm x 76 mm) |
| **Temperaturnøjagtighed** | ≤ 2 °C |

### Drifts-, opbevarings- og forsendelsesspecifikationer

| | Minimum | Maksimum |
|---|---|---|
| **Driftsspecifikationer** | | |
| Omgivende temperatur | 10 °C | 30 °C |
| Relativ luftfugtighed* | 25 % | 75 % |
| **Opbevarings- og forsendelsesspecifikationer** | | |
| Omgivende temperatur | -30 °C | 65 °C |
| Relativ luftfugtighed* | 10 % | 95 % |

* I overensstemmelse med MIL-STD-1695 skal den relative luftfugtighed være mellem 30 % og 70 % på steder, hvor elektroniske komponenter og hybride mikrokredsløb håndteres eller forarbejdes. MIL-STD-1695 stiller krav om den samme grad af kontroller af den relative luftfugtighed på områder til håndtering og opbevaring, med undtagelse af når emnerne er tildækkede eller beskyttede.

### EMC-oplysninger

TX *eco*-kablet er beregnet til brug i det elektromagnetiske miljø, som er beskrevet i *brugsanvisningen* til CARTO™ 3-systemet.

## FEJLFINDING

Hvis LED'en på TX *eco*-kablet er rød og blinker hurtigt, mislykkedes selvtesten og har forårsaget en fejl (se afsnittet *LED-status* i dette dokument). Følg nedenstående trin for at afhjælpe problemet.

1. Kobl kateteret fra kablet.
2. Kobl kablet fra CARTO™ 3-systemets patientgrænsefladeenhed.
3. Forbind kablet med patientgrænsefladeenheden igen.
4. Forbind kateteret med kablet igen.
5. Hvis der anvendes et QDOT MICRO™-modul, skal anvisningerne i *brugsanvisningen og produktbemærkningerne* til QDOT MICRO™-modulet følges.
6. Kontakt kundeservice eller Biosense Webster-repræsentanten, hvis problemet varer ved.

I visse situationer, hvor systemet udsættes for 15 kV luftudladning eller 8 kV kontaktudladning, viser CARTO™ 3-systemet 3 fejlmeddelelser samtidigt: Map points cannot be acquired (Kortlægningspunkter kan ikke indhentes) (Fejl 401), Patient Body Reference has moved (Patientens kropsreference har flyttet sig) (Fejl 256) og en pop-op-meddelelse om, at patientens kropsreference er ændret. Genstart patientgrænsefladeenheden, hvis dette sker.

## GARANTIFRASKRIVELSE OG ANSVARSBEGRÆNSNING

**DER ER INGEN UDTRYKT ELLER UNDERFORSTÅET GARANTI, HERUNDER UDEN BEGRÆNSNING EN HVILKEN SOM HELST UNDERFORSTÅET GARANTI AF SALGBARHED ELLER EGNETHED TIL ET BESTEMT FORMÅL, FOR DE(T) PRODUKT(ER), SOM ER BESKREVET HERI. BIOSENSE WEBSTER, INC. SKAL UNDER INGEN OMSTÆNDIGHEDER HOLDES ANSVARLIG FOR NOGEN SOM HELST SPECIEL, DIREKTE, HÆNDELIG ELLER ANDEN SKADE, MEDMINDRE DET UDTRYKKELIGT ER BESKREVET I EN SPECIFIK LOV.**

**UDEN BEGRÆNSNING AF FOREGÅENDE SKAL BIOSENSE WEBSTER, INC. ELLER DENS SØSTERSELSKABER IKKE VÆRE ANSVARLIG FOR NOGEN SPECIEL, DIREKTE, HÆNDELIG ELLER ANDEN SKADE SOM RESULTAT AF GENBRUG AF NOGEN PRODUKT(ER), SOM ER MARKERET TIL ENGANGSBRUG ELLER HVOR GENBRUG ER FORBUDT IFLG. GÆLDENDE LOV.**

Beskrivelser og specifikationer i Biosense Webster, Inc. tryksager, inklusive denne publikation har udelukkende til formål generelt at beskrive produktet på tidspunktet for fremstillingen og er ikke på nogen måde en udtrykkelig garanti af det beskrevne produkt.

## ELEKTRONISK BRUGSANVISNING

Dette dokument kan findes på www.e-ifu.com.

# TX *eco*-Kabel

**Achtung: Laut Bundesgesetz ist der Verkauf dieses Produktes in den USA nur durch einen zugelassenen Arzt oder auf ärztliche Anordnung gestattet.**

- Nicht verwenden, wenn die Verpackung geöffnet oder beschädigt ist.

## GERÄTEBESCHREIBUNG

Das TX *eco*-Kabel wird mit einem Verlängerungskabel verwendet, um einen therapeutischen Katheter von Biosense Webster mit der Patientenschnittstelle (Patient Interface Unit, PIU) des CARTO™ 3-Systems (Version 6 und neuer) zu verbinden. Die Verlängerungskabel sind nachfolgend aufgeführt:

- Für den QDOT™ Micro-Katheter: TX *eco* EXT-Kabel D135703
- Für andere therapeutische Katheter von Biosense Webster: D128603 (Katalognr. CR3434CT) oder D128604 (Katalognr. CR3425CT)

Das TX *eco*-Kabel übermittelt Daten vom therapeutischen Katheter von Biosense Webster an das CARTO™ 3-System und den HF-Generator. Die übermittelten Informationen werden weiter unten aufgeführt.

- Kraftsignale
- Positionssignale
- IC-Signale von den drei Mikroelektroden in der Spitze des Katheters (nur bei Kathetern mit Mikroelektroden)
- Temperaturmessungen von den sechs Thermoelementen in der Spitze des Katheters

## INDIKATIONEN

Das TX *eco*-Kabel wird verwendet, um einen therapeutischen Katheter von Biosense Webster mit der Patientenschnittstelle (Patient Interface Unit, PIU) des CARTO™ 3-Systems (Version 6 und neuer) zu verbinden.

## WARNHINWEISE

1. Lesen Sie vor der Verwendung dieses Kabels die *Bedienungsanleitung* für den therapeutischen Katheter von Biosense Webster. Wenn dieses Kabel mit dem QDOT MICRO™ Modul verwendet wird, lesen Sie bitte die *Bedienungsanleitung* für das CARTO™ 3-System sowie die *Bedienungsanleitung und die Versionshinweise* für das QDOT MICRO™ Modul, bevor Sie dieses Kabel mit dem QDOT MICRO™ Modul verbinden.
2. Dieses Kabel darf nur von Mitarbeitern, die diese Bedienungsanleitung gelesen und verstanden haben, eingerichtet und verwendet werden.
3. Dieses Kabel ist nur für die Verwendung mit einem therapeutischen Katheter von Biosense Webster validiert. Schließen Sie dieses Kabel an keinen anderen Katheter an.
4. Dieses Kabel ist nur für die Verwendung mit einem therapeutischen Katheter von Biosense Webster, einem kompatiblen HF-Generator, einem CARTO™ 3-System und Kabeln von Biosense Webster vorgesehen. Weitere Informationen erhalten Sie von Ihrem Biosense Webster Kundenbetreuer.
5. Dieses Kabel muss während des Verfahrens mindestens 1 Meter (39,4 Zoll) vom Positionsbestimmer des CARTO™ 3-Systems entfernt sein.
6. Dieses Kabel muss vor der Verwendung zum „Aufwärmen“ ca. 5 Minuten mit der PIU des CARTO™ 3-Systems verbunden werden, um exakte Temperaturmessungen sicherzustellen. Nach der Aufwärmphase stabilisieren sich die Temperaturmessungen. Wenn das Kabel vor Ende der Aufwärmphase verwendet wird, können abweichende Temperaturmessungen auftreten.

## INSTALLATION UND BEDIENUNG DES KABELS

### Befestigung des Kabelhalters

1. Positionieren Sie den Klemmteil des Kabelhalters (Teilenummer M652802) seitlich am Griff des CARTO™ Systemwagens oder über der Bettschiene. Drehen Sie dann den Knopf am Kabelhalter fest.
2. Führen Sie das Kabel von oben nach unten in den Kabelhalter ein.

### Anschließen des Kabels

1. Verbinden Sie den roten Stecker des Kabels mit der MAP-Buchse an der PIU des CARTO™ 3-Systems.
2. Verbinden Sie den gelben Stecker des Kabels mit der QUAD B- oder DECA-Buchse an der PIU.

   Hinweis 1: Beide Stecker müssen mit der PIU verbunden sein.

   Hinweis 2: Beim Verbinden des Steckers mit der QUAD A-Buchse kann unerwünschtes EKG-Rauschen auftreten.
3. Wenn Sie einen QDOT™ Micro-Katheter verwenden, verbinden Sie den Katheter mit einem Ende des TX *eco* EXT-Kabels. Verbinden Sie das andere Ende des TX *eco* EXT-Kabels mit der großen Buchse am Ende des TX *eco*-Kabels.
4. Schließen Sie bei Verwendung eines anderen therapeutischen Katheters von Biosense Webster den Katheter an ein Ende des Verlängerungskabels an. Verbinden Sie das andere Ende des Verlängerungskabels mit der kleinen runden Buchse am Ende des TX *eco*-Kabels.

### Trennen des Kabels

1. Trennen Sie den roten Stecker von der PIU des CARTO™ 3-Systems, indem Sie am Freigabegriff des Steckers ziehen.
2. Trennen Sie anschließend den gelben Stecker von der PIU, indem Sie am Freigabegriff des Steckers ziehen.

   Hinweis: Beide Stecker müssen von der PIU abgezogen werden. Es darf keiner der beiden Stecker verbunden bleiben.
3. Warten Sie nach dem Trennen des Kabels zehn Sekunden, bevor Sie das Kabel wieder mit der PIU verbinden.

### LED-Status

Der Status des Kabels wird durch eine LED angezeigt. Nachdem das Kabel ordnungsgemäß mit der PIU des CARTO™ 3-Systems und dem therapeutischen Katheter von Biosense Webster verbunden wurde, führt das Kabel einen integrierten Test (Built-In Test, BIT) durch.

| LED | Kabelstatus | Anmerkungen |
|---|---|---|
| Grün: blinkt langsam | BIT im Gange | --- |
| Grün: leuchtet dauerhaft | betriebsbereit | --- |
| Rot: blinkt schnell | Fehler, BIT fehlgeschlagen | Die Temperaturen werden nicht an das CARTO™ 3-System oder den HF-Generator gesendet.<br>Siehe Abschnitt *Fehlerbehebung* in diesem Dokument. |

## PFLEGE DES KABELS

### Reinigung

Das Kabel muss nicht desinfiziert oder sterilisiert werden. Das Kabel nicht mit Dampf reinigen, autoklavieren oder anderweitig sterilisieren.

Staub oder Schmutz wie folgt vom Kabel entfernen:

1. Das Kabel trennen.
2. Die Oberfläche des Kabels mit einem mit alkoholfreier Handseife und Wasser befeuchteten Tuch abwischen.
3. Sicherstellen, dass die Seifenlösung nicht in die Stecker oder Buchsen des Kabels eindringt.
4. Sicherstellen, dass das Kabel trocken ist, bevor es mit dem CARTO™ 3-System oder einem Katheter verbunden wird.

### Wartung

Keine Teile des Kabels können vom Benutzer gewartet werden. Wenn das Kabel nicht ordnungsgemäß funktioniert, setzen Sie sich mit dem Kundendienst in Verbindung oder bitten Sie Ihren Biosense Webster Kundenbetreuer um Ersatz. Die erwartete Nutzungsdauer des Kabels beträgt drei Jahre.

### Entsorgung

Das Produkt, dessen Einzelbestandteile und Abfallprodukte sind gemäß den örtlichen Vorschriften und Verordnungen zu entsorgen bzw. dem Recycling zuzuführen.

## TECHNISCHE DATEN

### Spezifikationen

| | |
|---|---|
| **DC-Eingang** | Das Kabel empfängt die Eingangsspannung von der PIU des CARTO™ 3-Systems. |
| **Gewicht** | 1 kg (2,2 lb) |
| **Abmessungen** | Länge 10 Zoll x Breite 1,9 Zoll x Höhe 3 Zoll (254 mm x 48 mm x 76 mm) |
| **Temperaturgenauigkeit** | ≤ 2 °C |

### Betriebs-, Lager- und Transportspezifikationen

| | Minimalwert | Maximalwert |
|---|---|---|
| **Betriebsdaten** | | |
| Umgebungstemperatur | 10 °C | 30 °C |
| Relative Luftfeuchtigkeit* | 25 % | 75 % |
| **Lager- und Transportbedingungen** | | |
| Umgebungstemperatur | –30 °C | 65 °C |
| Relative Luftfeuchtigkeit* | 10 % | 95 % |

* Gemäß MIL-STD-1695 muss die relative Luftfeuchtigkeit in Bereichen, in denen elektronische Bauteile und hybride Mikroschaltungen gehandhabt oder verarbeitet werden, zwischen 30 % und 70 % liegen. MIL-STD-1695 schreibt für Umschlags- und Lagerbereiche den gleichen relativen Luftfeuchtigkeitsbereich vor (außer wenn die Gegenstände abgedeckt oder geschützt sind).

### Informationen zur EMV

Das TX *eco*-Kabel ist zur Verwendung in elektromagnetischen Umgebungen gemäß der *Bedienungsanleitung* für das CARTO™ 3-System vorgesehen.

## FEHLERBEHEBUNG

Wenn die LED am TX *eco*-Kabel schnell rot blinkt, ist der BIT fehlgeschlagen und hat einen Fehler verursacht (siehe Abschnitt *LED-Status* in diesem Dokument). Befolgen Sie die nachfolgenden Schritte, um das Problem zu beheben.

1. Den Katheter vom Kabel trennen.
2. Das Kabel von der PIU des CARTO™ 3-Systems trennen.
3. Das Kabel wieder mit der PIU verbinden.
4. Den Katheter wieder mit dem Kabel verbinden.
5. Wenn ein QDOT MICRO™ Modul verwendet wird, befolgen Sie bitte die Anweisungen in der *Bedienungsanleitung und den Versionshinweisen* für das QDOT MICRO™ Modul.
6. Setzen Sie sich mit dem Kundendienst oder Ihrem Kundenbetreuer von Biosense Webster in Verbindung, wenn das Problem weiterhin besteht.

In manchen Fällen, wenn eine 15-kV-Luftentladung oder eine 8-kV-Kontaktentladung auf das System angewendet wird, werden auf dem CARTO™ 3-System gleichzeitig drei Fehlermeldungen angezeigt: Map-Punkte können nicht erfasst werden (Fehler 401), Referenzpunkte für die Körperposition des Patienten wurden verschoben (Fehler 256) und eine Pop-up-Meldung mit Angaben zu Veränderungen in den Referenzpunkten für die Körperposition des Patienten. Führen Sie in diesem Fall einen Neustart der PIU durch.

## HAFTUNGSAUSSCHLUSS UND BESCHRÄNKTE HAFTUNG

**ES BESTEHEN KEINERLEI AUSDRÜCKLICHE ODER STILLSCHWEIGENDE GARANTIEN FÜR DAS/DIE IN DIESER PUBLIKATION BESCHRIEBENE/N PRODUKT/E. DIES BEZIEHT SICH OHNE EINSCHRÄNKUNG AUF JEGLICHE STILLSCHWEIGENDE GARANTIEN DER MARKTFÄHIGKEIT ODER EIGNUNG FÜR EINEN BESTIMMTEN ZWECK.**
**BIOSENSE WEBSTER, INC. UND SEINE TOCHTERGESELLSCHAFTEN SIND KEINESFALLS FÜR IRGENDWELCHE DIREKTEN, SONDER-, NEBEN- ODER FOLGESCHÄDEN VERANTWORTLICH, SOWEIT NICHT DURCH BESTIMMTE GESETZE AUSDRÜCKLICH VORGESEHEN.**

**OHNE EINSCHRÄNKUNG DES VORHERGEHENDEN SIND BIOSENSE WEBSTER, INC. UND SEINE TOCHTERGESELLSCHAFTEN NICHT FÜR IRGENDWELCHE DIREKTEN, SONDER-, NEBEN- ODER FOLGESCHÄDEN VERANTWORTLICH, DIE SICH AUS DER WIEDERVERWENDUNG VON ENTSPRECHEND GEKENNZEICHNETEN PRODUKTEN FÜR DEN EINMALGEBRAUCH UND FÜR PRODUKTE ERGEBEN, DEREN WIEDERVERWENDUNG GESETZLICH NICHT ZULÄSSIG IST.**

Die Beschreibungen und Spezifikationen in den Biosense Webster, Inc. Druckmaterialien, einschließlich dieser Publikation, dienen lediglich zu Informationszwecken und sind nur dazu gedacht, das Produkt zum Zeitpunkt seiner Herstellung allgemein zu beschreiben. Sie stellen keine Garantieerklärung für das beschriebene Produkt dar.

## ELEKTRONISCHE GEBRAUCHSANWEISUNG

Dieses Dokument ist unter www.e-ifu.com abrufbar.

## Καλώδιο TX *eco*

**Προσοχή: Η ομοσπονδιακή νομοθεσία των Η.Π.Α. επιτρέπει την πώληση του παρόντος προϊόντος μόνο σε ιατρό ή κατόπιν εντ λής ιατρού.**

- Μην το χρησιμοποιήσετε εάν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά.

### ΠΕΡΙΓΡΑΦΗ ΟΥ ΠΡΟΪΟΝΤΟΣ

καλώδιο TX *eco* χρησιμοποιείται μαζί με ένα καλώδιο επέκτασης για τη σύνδεση θεραπευτικού καθετήρα της Biosense Webster στη μονάδα διασύνδεσης ασθενούς (PIU) του συστήματος CARTO™ 3 (Έκδ ση 6 και μεταγενέστερη). α καλώδια επέκτασης παρατίθενται παρακάτω:

- Για τον μικροκαθετήρα QDOT™: Καλώδιο TX *eco* EXT D135703
- Για άλλους θεραπευτικούς καθετήρες της Biosense Webster: D128603 (αρ. καταλόγ υ CR3434CT) ή D128604 (αρ. καταλόγ υ CR3425CT)

καλώδιο TX *eco* διαβιβάζει δεδ μένα από τον θεραπευτικό καθετήρα της Biosense Webster στ σύστημα CARTO™ 3 και τη γεννήτρια ραδιοσυχνοτήτων. Οι πληροφορίες που διαβιβάζονται παρατίθενται παρακάτω.

- Σήματα δύναμης
- Σήματα θέσης
- Σήματα IC από τα 3 μικροηλεκτρόδια στ άκρο του καθετήρα (μόνο για καθετήρες με μικροηλεκτρόδια)
- Μετρήσεις θερμοκρασίας από τα 6 θερμοζεύγη στ άκρ του καθετήρα

### ΕΝΔΕΙΞΕΙΣ ΡΗΣΗΣ

καλώδιο TX *eco* χρησιμοποιείται για τη σύνδεση θεραπευτικού καθετήρα της Biosense Webster στη μονάδα διασύνδεσης ασθενούς (PIU) του συστήματος CARTO™ 3 (Έκδ ση 6 και μεταγενέστερη).

### ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ

1. Πριν από τη χρήση του καλωδίου αυτ ύ, διαβάστε τις *Οδηγίες χρήσης* για τον θεραπευτικό καθετήρα της Biosense Webster. Εάν το καλώδιο αυτό χρησιμοποιείται με τη μονάδα QDOT MICRO™, ανατρέξτε στις *Οδηγίες χρήσης* για το σύστημα CARTO™ 3 και στις *Οδηγίες χρήσης και τις Σημειώσεις έκδοσης* για τη μονάδα QDOT MICRO™ πριν από τη χρήση αυτ ύ του καλωδί υ με τη μονάδα QDOT MICRO™.
2. Μόνο προσωπικό που έχει διαβάσει και κατανοήσει το περιεχόμενο αυτού του εγγράφου επιτρέπεται να εγκαταστήσει και να χρησιμοπ ιήσει το καλώδι αυτό.
3. καλώδιο αυτό είναι επικυρωμέν για χρήση μόν με θεραπευτικό καθετήρα της Biosense Webster. Μη συνδέετε αυτό το καλώδιο με οποιονδήπ τε άλλον καθετήρα.
4. καλώδιο αυτό προορίζεται για χρήση μόν με θεραπευτικό καθετήρα της Biosense Webster, συμβατή γεννήτρια ραδιοσυχνοτήτων, σύστημα CARTO™ 3, καθώς και καλώδια της Biosense Webster. Συμβουλευτείτε τον αντιπρόσωπο της Biosense Webster στην περιοχή σας για λεπτομέρειες.
5. καλώδιο αυτό πρέπει να βρίσκεται σε απόσταση τουλάχιστον 1 μέτρου (39,4 in) από την επιφάνεια εντοπισμού θέσης του συστήματος CARTO™ 3 κατά τη διάρκεια της διαδικασίας.
6. καλώδιο αυτό πρέπει να συνδεθεί στη μονάδα διασύνδεσης ασθεν ύς (PIU) του συστήματος CARTO™ 3 για μια περίοδο προθέρμανσης 5 λεπτών πριν από τη χρήση προκειμένου να διασφαλιστεί ότι λαμβάνονται ακριβείς μετρήσεις θερμοκρασίας. Μετά την περίοδο προθέρμανσης, οι μετρήσεις θερμοκρασίας σταθεροπ ι ύνται. Εάν το καλώδι χρησιμ ποιηθεί πριν το πέρας της περιόδου προθέρμανσης, ενδέχεται να προκύψει απόκλιση θερμοκρασίας.

### ΕΓΚΑΤΑΣ ΑΣΗ ΚΑΙ ΛΕΙΤΟΥΡΓΙΑ ΟΥ ΚΑΛΩΔΙΟΥ

#### Προσάρτηση του υποδοχέα καλωδί υ

1. Τοποθετήστε το τμήμα με σφιγκτήρα του υποδοχέα καλωδίου (κωδικός είδους M652802) στην πλευρά της λαβής του τροχήλατου του συστήματ ς CARTO™ ή επάνω από τη ράγα κλίνης. Στη συνέχεια, σφίξτε το περιστροφικό κουμπί που βρίσκεται στον υποδ χέα καλωδίου.
2. Εισαγάγετε το καλώδι στον υποδοχέα καλωδί υ με το καλώδιο στραμμένο προς τα κάτω.

#### Σύνδεση του καλωδί υ

1. Συνδέστε τον κόκκινο σύνδεσμο του καλωδίου στην υποδοχή MAP της μονάδας διασύνδεσης ασθεν ύς (PIU) του συστήματος CARTO™ 3.
2. Συνδέστε τον κίτρινο σύνδεσμ του καλωδίου στην υποδοχή QUAD B ή DECA στη μονάδα διασύνδεσης ασθενούς (PIU).

   Σημείωση 1: Πρέπει να συνδεθούν και οι δύ σύνδεσμοι στη μονάδα διασύνδεσης ασθενούς (PIU).

   Σημείωση 2: Η σύνδεση του συνδέσμου στην υποδοχή QUAD A μπορεί να προκαλέσει ανεπιθύμητ θόρυβ στ ΗΚΓ.
3. Εάν χρησιμ ποιείτε μικροκαθετήρα QDOT™, συνδέστε τον καθετήρα στ ένα άκρο του καλωδίου επέκτασης TX *eco* EXT. Συνδέστε το άλλ άκρ του καλωδίου επέκτασης TX *eco* EXT στη μεγάλη υποδοχή που βρίσκεται στ άκρ του καλωδίου TX *eco*.
4. Εάν χρησιμ ποιείτε κάποιον άλλο θεραπευτικό καθετήρα της Biosense Webster, συνδέστε τον καθετήρα στ ένα άκρ του καλωδίου επέκτασης. Συνδέστε το άλλο άκρο του καλωδίου επέκτασης στη μικρή στρογγυλή υποδοχή που βρίσκεται στο άκρο του καλωδίου TX *eco*.

#### Αποσύνδεση του καλωδί υ

1. Αποσυνδέστε τον κόκκινο σύνδεσμ από τη μονάδα διασύνδεσης ασθενούς (PIU) του συστήματος CARTO™ 3 τραβώντας τον σύνδεσμο από τη λαβή απελευθέρωσης με ολίσθηση.
2. Στη συνέχεια, αποσυνδέστε τον κίτρινο σύνδεσμ από τη μονάδα διασύνδεσης ασθεν ύς (PIU) τραβώντας τον σύνδεσμ από τη λαβή απελευθέρωσης με ολίσθηση.

   Σημείωση: Πρέπει να αποσυνδεθούν και οι δύ σύνδεσμοι από τη μονάδα διασύνδεσης ασθεν ύς (PIU). Μην αφήνετε το ένα καλώδιο συνδεδεμέν και το άλλο αποσυνδεδεμέν .
3. Μετά την αποσύνδεση του καλωδί υ, περιμένετε για 10 δευτερόλεπτα πριν επανασυνδέσετε το καλώδιο στη μονάδα διασύνδεσης ασθεν ύς (PIU).

#### Κατάσταση LED

Η κατάσταση του καλωδίου υποδεικνύεται από μια ενδεικτική λυχνία LED. Αφ ύ το καλώδι συνδεθεί σωστά στη μονάδα διασύνδεσης ασθενή (PIU) του συστήματος CARTO™ 3 και στ ν θεραπευτικό καθετήρα της Biosense Webster, το καλώδιο πραγματοποιεί έναν ενσωματωμένο έλεγχο (BIT).

| LED | Κατάσταση καλωδίου | Σχόλια |
|---|---|---|
| Πράσινο: αναβ σβήνει αργά | BIT σε εξέλιξη | --- |
| Πράσινο: σταθερό | Έτοιμο για χρήση | --- |
| Κόκκινο: αναβοσβήνει γρήγορα | Σφάλμα, αποτυχία BIT | Οι θερμοκρασίες δεν αποστέλλονται στο σύστημα CARTO™ 3 ή στη γεννήτρια RF.<br>Δείτε την ενότητα *Αντιμετώπιση προβλημάτων* σε αυτό το έγγραφο. |

### ΦΡΟΝΤΙΔΑ ΟΥ ΚΑΛΩΔΙΟ

#### Καθαρισμός

καλώδιο δεν απαιτεί απολύμανση ή αποστείρωση. Μην υποβάλετε σε αποστείρωση με ατμό ή με αυτόκαυστο ούτε να απ στειρώνετε το καλώδιο με άλλες μεθόδους.

Εάν υπάρχ υν σκόνη ή υπολείμματα επάνω στο καλώδι , καθαρίστε το καλώδιο ως εξής:

1. Αποσυνδέστε το καλώδιο.
2. Καθαρίστε το εξωτερικό μέρος του καλωδί υ σκουπίζοντάς το με ένα πανί νοτισμέν με σαπ ύνι χεριών χωρίς αλκοόλη και νερό.
3. Διασφαλίστε ότι το διάλυμα σαπ υνιού δεν έχει εισχωρήσει στους συνδέσμους του καλωδίου ή στα βύσματα.
4. Διασφαλίστε ότι το καλώδιο είναι στεγνό πριν το συνδέσετε στο σύστημα CARTO™ 3 ή σε κάποιον καθετήρα.

#### Συντήρηση

καλώδιο δεν περιλαμβάνει εξαρτήματα που επιδέχονται συντήρηση από τον χρήστη. Εάν το καλώδιο παρ υσιάσει αστοχία στη λειτουργία του, επικοινωνήστε με την υποστήριξη πελατών ή τον τοπικό σας αντιπρόσωπ της Biosense Webster για αντικατάσταση. Η αναμενόμενη ωφέλιμη διάρκεια ζωής του καλωδίου είναι τρία έτη.

#### Απόρριψη

Ανακυκλώστε τα εξαρτήματα ή απορρίψτε το προϊόν και τα εναπομείναντα τμήματά του ή τα απόβλητα σύμφωνα με τους τοπικούς νόμους και κανονισμούς.

### ΕΧ ΝΙΚΑ ΔΕΔΟΜΕΝΑ

#### Προδιαγραφές

| | |
|---|---|
| **Είσ δος DC** | καλώδιο λαμβάνει ισχύ από τη μονάδα διασύνδεσης ασθεν ύς (PIU) του συστήματος CARTO™ 3. |
| **Βάρος** | 1 kg (2,2 lb) |
| **Διαστάσεις** | 10 in μήκος x 1,9 in πλάτος x 3 in ύψος<br>(254 mm x 48 mm x 76 mm) |
| **Ακρίβεια θερμοκρασίας** | ≤ 2 °C |

#### Προδιαγραφές λειτουργίας, αποθήκευσης και μεταφ ράς

| | Ελάχιστη | Μέγιστη |
|---|---|---|
| **Προδιαγραφές λειτουργίας** | | |
| Θερμοκρασία περιβάλλ ντ ς | 10 °C | 30 °C |
| Σχετική υγρασία* | 25% | 75% |
| **Προδιαγραφές αποθήκευσης και μεταφ ράς** | | |
| Θερμοκρασία περιβάλλ ντ ς | -30 °C | 65 °C |
| Σχετική υγρασία* | 10% | 95% |

* Σύμφωνα με το πρότυπο MIL-STD-1695, τα επίπεδα σχετικής υγρασίας πρέπει να βρίσκονται εντός του εύρ υς 30% έως 70% στους χώρους χειρισμού ή επεξεργασίας ηλεκτρονικών εξαρτημάτων ή υβριδικών μικροκυκλωμάτων. πρότυπ MIL-STD-1695 απαιτεί το ίδιο επίπεδο ελέγχων σχετικής υγρασίας για τους χώρ υς χειρισμούς και φύλαξης, εκτός εάν τα στ ιχεία είναι καλυμμένα ή προστατευμένα.

#### Πληροφορίες για την ηλεκτρομαγνητική συμβατότητα (EMC)

καλώδιο TX *eco* προορίζεται για χρήση στο ηλεκτρομαγνητικό περιβάλλον που καθορίζεται στις *Οδηγίες χρήσης* για το σύστημα CARTO™ 3.

### ΑΝΤΙΜΕΤΩΠΙΣΗ ΠΡΟΒΛΗΜΑ Ν

Εάν η ενδεικτική λυχνία LED στ καλώδι TX *eco* είναι κόκκινη και αναβ σβήνει γρήγορα, έλεγχος BIT έχει αποτύχει και έχει προκαλέσει σφάλμα (βλ. ενότητα *Κατάσταση LED* στ παρόν έγγραφο). Ακολουθήστε τα παρακάτω βήματα για να διορθώσετε το πρόβλημα.

1. Αποσυνδέστε τον καθετήρα από το καλώδι .
2. Αποσυνδέστε το καλώδιο από τη μονάδα διασύνδεσης ασθενούς (PIU) του συστήματος CARTO™ 3.
3. Επανασυνδέστε το καλώδιο στη μονάδα διασύνδεσης ασθενούς (PIU).
4. Επανασυνδέστε τον καθετήρα στο καλώδιο.
5. Εάν χρησιμοπ ιείται μονάδα QDOT MICRO™, ακολουθήστε τις οδηγίες που περιέχονται στις *Οδηγίες χρήσης και τις Σημειώσεις έκδοσης* για τη μονάδα QDOT MICRO™.
6. Εάν το πρόβλημα παραμένει, επικοινωνήστε με την υποστήριξη πελατών ή τον αντιπρόσωπό σας της Biosense Webster.

Σε ορισμένες περιπτώσεις, όπου εφαρμόζονται στο σύστημα 15 kV εκκένωσης στον αέρα ή 8 kV εκκένωσης από επαφή, το σύστημα CARTO™ 3 εμφανίζει 3 μηνύματα σφάλματ ς ταυτόχρονα: Map points cannot be acquired (Δεν είναι δυνατή η συλλογή σημείων χάρτη) (Σφάλμα 401), Patient Body Reference has moved ( σύστημα αναφοράς σώματ ς ασθενούς μετακινήθηκε) (Σφάλμα 256) και ένα αναδυόμενο μήνυμα που υποδεικνύει την αλλαγή στ σύστημα αναφοράς σώματ ς ασθενούς. Αν συμβεί κάτι τέτοι , επανεκκινήστε τη μονάδα διασύνδεσης ασθενούς (PIU).

## ΑΠΟΠΟΙΗΣΗ ΕΓΓ ΗΣΗΣ ΚΑΙ ΠΕΡΙΟΡΙΣΜΟΣ ΕΥΘΥΝΗΣ

**ΔΕΝ ΥΠΑΡΧΕΙ ΑΜΕΣΗ Ή ΕΜΜΕΣΗ ΕΓΓΥΗΣΗ, ΣΥΜΠΕΡΙΛΑΜΒΑΝΟΜΕΝΗΣ ΡΙΣ ΠΕΡΙΟΡΙΣΜΟΥΣ ΟΠΟΙΑΣ ΕΜΜΕΣΗΣ ΕΓΓΥΗΣΗΣ ΕΜΠΟΡΕΥΣΙΜΟΤΗ ΑΣ Ή ΚΑ ΑΛΛΗΛΟΤΗ ΑΣ ΣΤΟ ΠΡΟΪΟΝ Ή ΠΡΟΪΟΝΤΑ ΠΟΥ ΠΕΡΙΓΡΑΦΟΝΤΑΙ ΣΤΟ ΠΑΡΟΝ ΕΝΤΥΠΟ. ΣΕ ΚΑΜΙΑ ΠΕΡΙΠΤΩΣΗ Η BIOSENSE WEBSTER, INC. Ή ΟΙ ΘΥΓΑΤΡΙΚΕΣ ΤΗΣ ΕΤΑΙΡΙΕΣ ΔΕΝ ΦΕΡΟΥΝ ΕΥΘΥΝΗ ΓΙΑ ΟΠΟΙΕΣΔΗΠΟΤΕ ΕΙΔΙΚΕΣ, ΑΜΕΣΕΣ, ΑΠΟΘΕΤΙΚΕΣ, ΠΑΡΕΠΟΜΕΝΕΣ Ή ΑΛΛΕΣ ΖΗΜΙΕΣ ΕΚ ΟΣ ΑΠΟ ΕΚΕΙΝΕΣ ΠΟΥ ΟΡΙΖΟΝΤΑΙ ΚΑΤΗΓΟΡΗΜΑΤΙΚΑ ΑΠΟ ΤΗΝ ΙΣΧΥΟΥΣΑ ΝΟΜΟΘΕΣΙΑ.**

**ΧΩΡΙΣ ΝΑ ΠΕΡΙΟΡΙΖΟΝΤΑΙ ΤΑ ΠΡΟΑΝΑΦΕΡΟΜΕΝΑ ΣΕ ΚΑΜΙΑ ΠΕΡΙΠ ΩΣΗ Η BIOSENSE WEBSTER, INC. ΔΕΝ ΘΑ ΕΙΝΑΙ ΥΠΕΥΘΥΝΗ ΓΙΑ ΟΠΟΙΕΣΔΗΠΟ Ε ΕΙΔΙΚΕΣ, ΑΜΕΣΕΣ, ΑΠΟΘΕ ΙΚΕΣ, ΠΑΡΕΠΟΜΕΝΕΣ Ή ΑΛΛΕΣ ΖΗΜΙΕΣ ΠΟΥ ΜΠΟΡΕΙ ΝΑ ΠΡΟΚΛΗΘΟΥΝ ΑΠΟ ΤΗΝ ΕΠΑΝΑΧΡΗΣΙΜΟΠΟΙΗΣΗ Ο ΠΡΟΪΟΝΤΟΣ Ή ΠΡΟΪΟΝΤ Ν ΠΟΥ ΠΡΟΟΡΙΖΟΝΤΑΙ ΓΙΑ ΜΙΑ ΧΡΗΣΗ Ή ΟΠΟ Η ΕΠΑΝΑΧΡΗΣΙΜΟΠΟΙΗΣΗ ΑΠΑΓΟΡΕΥΕ ΑΙ ΑΠΟ ΙΣ ΟΝ ΕΣ ΝΟΜΟΥΣ.**

Οι περιγραφές και προδιαγραφές που αναφέρονται στα έντυπα της εταιρίας Biosense Webster, Inc., συμπεριλαμβανομένου του παρόντος εντύπου, σκοπό έχουν μόν ν την πληροφόρηση και την γενική περιγραφή του προϊόντος κατά την χρονική στιγμή της κατασκευής του και δεν προορίζονται σε καμία περίπτωση ως εγγύηση που αφορά το συνταγ γραφούμενο προϊόν.

## ΗΛΕΚΤΡΟΝΙΚΕΣ ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

παρόν έγγραφ είναι διαθέσιμο στον ιστότοπο www.e-ifu.com.

# Cable TX *eco*

**Precaución: Las leyes federales de los EE. UU. permiten la venta de este dispositivo solo a un médico titulado o con receta médica.**

- No utilizar si el paquete está abierto o dañado.

## DESCRIPCIÓN DEL DISPOSITIVO

El cable TX *eco* se utiliza con un cable de extensión para conectar un catéter terapéutico Biosense Webster a la unidad de interfaz del paciente (PIU) del sistema CARTO™ 3 (versión 6 y posteriores). Los cables de extensión se enumeran a continuación:

- Para el microcatéter QDOT™: cable TX *eco* EXT D135703
- Para otros catéteres terapéuticos Biosense Webster: D128603 (n.º de catálogo CR3434CT) o D128604 (n.º de catálogo CR3425CT)

El cable TX *eco* transmite los datos del catéter terapéutico Biosense Webster al sistema CARTO™ 3 y al generador de RF. A continuación se indica la información transmitida.

- Señales de fuerza
- Señales de ubicación
- Señales IC de los 3 microelectrodos de la punta del catéter (solo para catéteres con microelectrodos)
- Mediciones de temperatura de los 6 termopares de la punta del catéter

## INDICACIONES DE USO

El cable TX *eco* se usa para conectar un catéter terapéutico Biosense Webster a la unidad de interfaz del paciente (PIU) del sistema CARTO™ 3 (versión 6 y posteriores).

## ADVERTENCIAS

1. Antes de usar este cable, lea las *instrucciones de uso* del catéter terapéutico Biosense Webster. Si este cable se utiliza con el módulo QDOT MICRO™, consulte las *instrucciones de uso* del sistema CARTO™ 3 y las *instrucciones de uso y las notas sobre la versión* del módulo QDOT MICRO™ antes de emplear este cable con el módulo QDOT MICRO™.
2. Solo el personal que haya leído y entendido el contenido de estas instrucciones de uso puede configurar y usar este cable.
3. Este cable se ha validado solo para su uso con un catéter terapéutico Biosense Webster. No conecte este cable a un catéter distinto.
4. Este cable está diseñado para utilizarse únicamente con un catéter terapéutico Biosense Webster, generadores RF compatibles, un sistema CARTO™ 3 y cables de Biosense Webster. Para obtener más detalles, consulte a su representante de Biosense Webster.
5. Este cable debe estar a al menos 1 metro (39,4 pulgadas) de distancia del triángulo de localización del sistema CARTO™ 3 durante el procedimiento.
6. Este cable se debe conectar a la PIU del sistema CARTO™ 3 durante un periodo de calentamiento de 5 minutos antes de su uso para garantizar la precisión de las lecturas de temperatura. Después del periodo de calentamiento, dichas lecturas se estabilizan. Si se usa el cable antes de que finalice el periodo de calentamiento, se podría producir una desviación de la temperatura.

## INSTALACIÓN Y MANEJO DEL CABLE

### Fijación del soporte del cable

1. Coloque la parte de la abrazadera del soporte del cable (número de referencia M652802) en el lateral del mango del carro del sistema CARTO™ o sobre la barra de la cama. A continuación, apriete el botón del soporte del cable.
2. Introduzca el cable en el soporte con el cable hacia abajo.

### Conexión del cable

1. Conecte el conector rojo del cable en el puerto MAP de la PIU del sistema CARTO™ 3.
2. Conecte el conector amarillo del cable en el puerto QUAD B o DECA de la PIU.

   Nota 1: Ambos conectores se deben conectar a la PIU.

   Nota 2: Si conecta el conector en el puerto QUAD A, se puede producir un ruido de ECG no deseado.
3. Si utiliza un microcatéter QDOT™, conecte el catéter a un extremo del cable TX *eco* EXT. Conecte el otro extremo del cable TX *eco* EXT al puerto grande situado en el extremo del cable TX *eco*.
4. Si utiliza otro catéter terapéutico Biosense Webster, conecte el catéter a un extremo del cable de extensión. Conecte el otro extremo del cable de extensión al puerto redondo pequeño situado en el extremo del cable TX *eco*.

### Desconexión del cable

1. Desconecte el conector rojo de la PIU del sistema CARTO™ 3 tirando de él desde la empuñadura de liberación deslizante.
2. A continuación, desconecte el conector amarillo de la PIU tirando de él desde la empuñadura de liberación deslizante.

   Nota: Ambos conectores se deben desconectar de la PIU. No deje un cable conectado y el otro no.
3. Tras desconectar el cable, espere 10 segundos antes de volver a conectar el cable a la PIU.

### Estado del LED

El estado del cable se indica a través de un LED. Una vez que el cable se ha conectado correctamente a la PIU del sistema CARTO™ 3 y al catéter terapéutico Biosense Webster, el cable realiza un test de autodiagnóstico (BIT).

| LED | Estado del cable | Comentarios |
|---|---|---|
| Verde: parpadeo lento | BIT en curso | --- |
| Verde: fijo | Listo para usar | --- |
| Rojo: parpadeo rápido | Error, BIT fallida | No se envían temperaturas al sistema CARTO™ 3 ni al generador de RF.<br>Consulte la sección *Solución de problemas* de este documento. |

## CUIDADO DEL CABLE

### Limpieza

El cable no precisa desinfección ni esterilización. No esterilice el cable con vapor, en autoclave ni de ninguna otra forma.

Si el cable presenta polvo o residuos, límpielo de la siguiente forma:

1. Desconecte el cable.
2. Limpie la parte exterior del cable con un paño humedecido con jabón de manos sin alcohol y agua.
3. Asegúrese de que no entre solución jabonosa en los conectores del cable ni en los puertos.
4. Asegúrese de que el cable esté seco antes de conectarlo al sistema CARTO™ 3 o a un catéter.

### Mantenimiento

El cable no contiene piezas que pueda reparar el usuario. Si el cable no funciona, póngase en contacto con Servicio al cliente o con su representante de Biosense Webster para cambiarlo. La vida útil prevista del cable es de tres años.

### Eliminación

Recicle los componentes o elimine el producto y sus elementos residuales o de desecho según exigen las leyes y reglamentos locales.

## DATOS TÉCNICOS

### Especificaciones

| | |
|---|---|
| **Entrada de CC** | El cable recibe alimentación eléctrica de la PIU del sistema CARTO™ 3. |
| **Peso** | 1 kg (2,2 lb) |
| **Dimensiones** | 10 pulgadas de longitud x 1,9 pulgadas de ancho x 3 pulgadas de alto (254 mm x 48 mm x 76 mm) |
| **Precisión de la temperatura** | ≤2 °C |

### Especificaciones de funcionamiento, almacenamiento y envío

| | Mínima | Máxima |
|---|---|---|
| **Especificaciones de funcionamiento** | | |
| Temperatura ambiente | 10 °C | 30 °C |
| Humedad relativa* | 25 % | 75 % |
| **Especificaciones de almacenamiento y envío** | | |
| Temperatura ambiente | -30 °C | 65 °C |
| Humedad relativa* | 10 % | 95 % |

* De acuerdo con MIL-STD-1695, los niveles de humedad relativa se deben encontrar entre el 30 % y el 70 % en áreas donde se manipulen o se procesen piezas electrónicas y microcircuitos híbridos. MIL-STD-1695 exige el mismo nivel de control de humedad relativa para las áreas de manipulación y almacenamiento, salvo si se cubren o se protegen los elementos.

### Información sobre EMC

El cable TX *eco* está diseñado para utilizarse en el entorno electromagnético especificado en las *Instrucciones de uso* del sistema CARTO™ 3.

## SOLUCIÓN DE PROBLEMAS

Si el LED del cable TX *eco* está rojo y parpadea rápido, el BIT ha fallado y ha provocado un error (consulte la sección *LED de estado* de este documento). Siga los pasos a continuación para resolver el problema.

1. Desconecte el catéter del cable.
2. Desconecte el cable de la PIU del sistema CARTO™ 3.
3. Vuelva a conectar el cable a la PIU.
4. Vuelva a conectar el catéter al cable.
5. Si utiliza un módulo QDOT MICRO™, siga las indicaciones de las *Instrucciones de uso y Notas de la versión* del módulo QDOT MICRO™.
6. Si el problema persiste, póngase en contacto con Servicio al cliente o con su representante de Biosense Webster.

En algunas situaciones, si el sistema recibe 15 kV de descarga por aire u 8 kV de descarga por contacto, el sistema CARTO™ 3 muestra 3 mensajes de error simultáneamente: no se pueden adquirir puntos del mapa (error 401), la referencia del cuerpo del paciente se ha movido (error 256) y un mensaje emergente que indica el cambio de referencia del cuerpo del paciente. Si ocurriera esto, reinicie la PIU.

## RESTRICCIÓN DE GARANTÍA Y DE RECURSO LEGAL

**NO EXISTE NINGUNA GARANTÍA EXPRESA O IMPLÍCITA EN LOS PRODUCTOS DESCRITOS EN ESTA PUBLICACIÓN, INCLUYENDO, SIN LIMITACIÓN, NINGUNA GARANTÍA IMPLÍCITA DE COMERCIABILIDAD O ADECUACIÓN PARA UN PROPÓSITO DETERMINADO. EN NINGÚN CASO SE HARÁ RESPONSABLE A BIOSENSE WEBSTER, INC., NI A SUS COMPAÑÍAS AFILIADAS, DE DAÑOS ESPECIALES, DIRECTOS, INCIDENTALES, RESULTANTES U OTROS DAÑOS, EXCEPTO DE AQUELLOS DISPUESTOS EXPRESAMENTE POR LA LEY.**

**SIN LIMITARSE A LO ANTEDICHO, NI BIOSENSE WEBSTER, INC. NI NINGUNA DE SUS COMPAÑÍAS AFILIADAS SERÁN RESPONSABLES DE NINGÚN DAÑO ESPECIAL, DIRECTO, RESULTANTE, CONSECUENTE, NI OTRO TIPO DE DAÑOS QUE SURJA POR LA REUTILIZACIÓN DE CUALQUIER PRODUCTO O PRODUCTOS ETIQUETADOS PARA UN SOLO USO O CUYA REUTILIZACIÓN SE PROHÍBA POR LEY.**

Las descripciones y especificaciones que aparecen en la documentación de Biosense Webster, Inc., inclusive esta publicación, tienen solamente un propósito informativo, su única finalidad es describir el producto de manera general en el momento de su fabricación y no constituyen ninguna garantía expresa.

**INSTRUCCIONES DE USO ELECTRÓNICAS**

Este documento está disponible en www.e-ifu.com.

# TX *eco* kaabel

**Hoiatus. Föderaalseaduse (USA) järgi võib seda seadet müüa vaid litsentseeritud tervishoiutöötaja või tema tellimusel.**

- Ärge kasutage, kui pakend on avatud või kahjustatud.

## SEADME KIRJELDUS

TX *eco* kaablit kasutatakse koos pikenduskaabliga Biosense Websteri terapeutilise kateetri ja CARTO™ 3 süsteemi (versioon 6 ja uuemad) patsiendiliidese (PIU) ühendamiseks. Pikenduskaablid on loetletud allpool.

- Kateetri QDOT™ Micro puhul: TX *eco* EXT kaabel D135703
- Teiste Biosense Websteri terapeutiliste kateetrite puhul: D128603 (kataloogi nr CR3434CT) või D128604 (kataloogi nr CR3425CT)

TX *eco* kaabel edastab andmed Biosense Websteri terapeutilisest kateetrist CARTO™ 3 süsteemile ja raadiosagedusgeneraatorile. Allpool on loetletud edastatavad andmed.

- Jõusignaalid
- Asukoha signaalid
- IC-signaalid kateetri otsakus olevalt kolmelt mikroelektroodilt (ainult mikroelektroodidega kateetritel)
- Temperatuuriandmed kateetri otsakus olevalt kuuelt termopaartajurilt

## KASUTUSNÄIDUSTUSED

TX *eco* kaablit kasutatakse Biosense Websteri terapeutilise kateetri ja CARTO™ 3 süsteemi (versioon 6 ja uuemad) patsiendiliidese (PIU) ühendamiseks.

## HOIATUSED

1. Enne selle kaabli kasutamist lugege läbi Biosense Websteri terapeutilise kateetri *kasutusjuhend*. Juhul kui kasutate seda kaablit koos QDOT MICRO™ mooduliga, siis lugege enne selle kaabli kasutamist koos QDOT MICRO™ mooduliga läbi CARTO™ 3 süsteemi *kasutusjuhend* ning QDOT MICRO™ mooduli *kasutusjuhend ja väljalaskemärkmed*.
2. Seda kaablit tohivad paigaldada ja kasutada ainult selle dokumendi sisu lugenud ja sellest aru saanud töötajad.
3. Seda kaablit võib kasutada ainult koos Biosense Websteri terapeutilise kateetriga. Ärge ühendage kaablit mis tahes teiste kateetritega.
4. See kaabel on mõeldud kasutamiseks ainult Biosense Websteri terapeutilise kateetriga, ühilduva RF-generaatoriga, CARTO™ 3 süsteemiga ja Biosense Websteri kaablitega. Üksikasjalikuma teabe saamiseks võtke ühendust Biosense Websteri esindajaga.
5. See kaabel peab protseduuri ajal olema CARTO™ 3 süsteemist vähemalt 1 meetri (39,4 tolli) kaugusel.
6. Täpsete temperatuurinäitude tagamiseks peab see kaabel pärast CARTO™ 3 süsteemi patsiendiliidesega (PIU-ga) ühendamist 5 minutit soojenema. Temperatuurinäidud stabiliseeruvad pärast soojendusperioodi. Kui kaablit kasutatakse enne soojendusperioodi lõppu, võib esineda temperatuurikõikumisi.

## KAABLI PAIGALDAMINE JA KASUTAMINE

### Kaablihoidiku kinnitamine

1. Asetage kaablihoidiku klambriosa (tootenumber M652802) CARTO™ süsteemi käru käepideme kõrvale või üle voodipiirde. Seejärel pingutage kaablihoidikul olevat nuppu.
2. Sisestage kaabel hoidikusse nii, et kaabel oleks suunaga allapoole.

### Kaabli ühendamine

1. Ühendage kaabli punane pistmik CARTO™ 3 süsteemi patsiendiliidese MAP-pesasse.
2. Ühendage kaabli kollane pistmik patsiendiliidese QUAD B- või DECA-pesasse.

   Märkus 1. Mõlemad pistmikud peavad olema patsiendiliidesega ühendatud.

   Märkus 2. Pistmiku ühendamine QUAD A pesasse võib põhjustada soovimatut EKG müra.
3. Kateetri QDOT™ Micro kasutamise korral ühendage kateeter TX *eco* EXT kaabli ühe otsaga. Ühendage TX *eco* EXT kaabli teine ots TX *eco* kaabli otsas olevasse suurde pessa.
4. Muu Biosense Websteri terapeutilise kateetri kasutamise korral ühendage kateeter pikenduskaabli ühe otsaga. Ühendage pikenduskaabli teine ots TX *eco* kaabli otsas olevasse väikesesse ümmargusse pessa.

### Kaabli lahutamine

1. Lahutage punane pistmik CARTO™ 3 süsteemi patsiendiliidesest, tõmmates pistmikku libisevast otsakust.
2. Seejärel lahutage kollane pistmik patsiendiliidesest, tõmmates pistmikku libisevast otsakust.

   Märkus. Mõlemad pistmikud tuleb patsiendiliidesest lahutada. Ärge hoidke üht kaablit ühendatuna ja teist lahutatuna.
3. Pärast kaabli lahutamist oodake 10 sekundit ja alles siis taasühendage kaabel patsiendiliidesega.

### LED-i olek

Kaabli olekule osutab LED-tuli. Kui kaabel on CARTO™ 3 süsteemi patsiendiliidese ja Biosense Websteri terapeutilise kateetriga õigesti ühendatud, sooritab kaabel sisetesti (BIT).

| LED | Kaabli olek | Kommentaarid |
|---|---|---|
| Roheline: vilgub aeglaselt | Toimub BIT | --- |
| Roheline: põleb pidevalt | Kasutamiseks valmis | --- |
| Punane: vilgub kiiresti | Viga, BIT nurjus | Temperatuurinäite ei saadeta süsteemi CARTO™ 3 või raadiosagedusgeneraatorisse.<br>Vaadake selle dokumendi jaotist *Veaotsing*. |

## KAABLI HOOLDAMINE

### Puhastamine

Kaablit pole vaja desinfitseerida ega steriliseerida. Ärge aurutage, autoklaavige ega steriliseerige kaablit muul moel.

Kui kaablile satub tolmu või prahti, puhastage kaabel järgmiselt.

1. Lahutage kaabel.
2. Puhastage kaabli väliskülg alkoholivabas seebivees niisutatud lapiga.
3. Veenduge, et seebilahust ei satuks kaablipistmikesse või kaablipesadesse.
4. Veenduge enne kaabli CARTO™ 3 süsteemi või kateetriga ühendamist, et kaabel oleks kuiv.

### Hooldus

Kaablil pole osi, mida kasutaja hooldada tohiks. Kui kaabel ei tööta, võtke asendusjuhtme tellimiseks ühendust klienditoe või oma Biosense Websteri esindajaga. Kaabli oodatav kasutusiga on kolm aastat.

### Kasutuselt kõrvaldamine

Töödelge komponendid ümber või hävitage toode ja selle jääkkomponendid või jäätmed kohalike seaduste ning eeskirjade järgi.

## TEHNILISED ANDMED

### TEHNILINE KIRJELDUS

| | |
|---|---|
| **Alalisvoolusisend** | Kaabel saab toidet CARTO™ 3 süsteemi patsiendiliidesest. |
| **Kaal** | 1 kg (2,2 naela) |
| **Mõõtmed** | Pikkus 10 tolli × laius 1,9 tolli × kõrgus 3 tolli (254 mm × 48 mm × 76 mm) |
| **Temperatuuri täpsus** | ≤ 2 °C |

### Kasutamis-, hoiustamis- ja transpordispetsifikatsioonid

| | Minimaalne | Maksimaalne |
|---|---|---|
| **Kasutamisspetsifikatsioonid** | | |
| Ümbritseva keskkonna temperatuur | 10 °C | 30 °C |
| Suhteline õhuniiskus* | 25% | 75% |
| **Hoiustamis- ja transpordispetsifikatsioonid** | | |
| Ümbritseva keskkonna temperatuur | –30 °C | 65 °C |
| Suhteline õhuniiskus* | 10% | 95% |

* Standardi MIL-STD-1695 kohaselt peab suhtelise õhuniiskuse tase elektroonikadetailide ja hübriid-mikrolülituste käsitsus- ja töötluskohtades jääma 30% ja 70% vahele. Standardi MIL-STD-1695 järgi peab suhtelise õhuniiskuse tase olema käsitsus- ja hoiustusruumides sama, v.a juhul kui esemed on kaetud või kaitstud.

### Elektromagnetilise ühilduvuse (EMC) teave

TX *eco* kaabel on mõeldud kasutamiseks elektromagnetilises keskkonnas, mis on täpsustatud CARTO™ 3 süsteemi *kasutusjuhendis*.

## VEAOTSING

Kui TX *eco* kaabli LED-tuli on punane ja vilgub kiiresti, siis on BIT nurjunud ja põhjustanud vea (vt selle dokumendi jaotist *LED-i olek*). Probleemi lahendamiseks järgige allolevaid juhiseid.

1. Lahutage kateeter kaablist.
2. Lahutage kaabel CARTO™ 3 süsteemi patsiendiliidesest.
3. Ühendage kaabel uuesti patsiendiliidesega.
4. Ühendage kateeter uuesti kaabliga.
5. Kui kasutate moodulit QDOT MICRO™, siis järgige mooduli QDOT MICRO™ *kasutusjuhendit ja redaktsioonimärkmetes* esitatud juhiseid.
6. Kui probleem ei lahene, võtke ühendust klienditoe või Biosense Websteri esindajaga.

Kui süsteemile kantakse 15 kV õhulaengut või 8 kV kontaktilaengut, kuvab CARTO™ 3 süsteem teatud juhtudel samal ajal kolme veateadet: „Map points cannot be acquired (Error 401)“ (Kaardipunkte ei õnnestu hõivata (viga 401)), „Patient Body Reference has moved (Error 256)“ (Patsiendi kehaviide on liikunud (viga 256)) ja hüpikteade, mis näitab patsiendi kehaviite muutust. Sellisel juhul taaskäivitage patsiendiliides (PIU).

## GARANTIIST LAHTIÜTLEMINE JA VASTUTUSE PIIRID

**TOO(DE)TELE EI LAIENE ÜKSKI OTSENE EGA KAUDNE GARANTII KAASA ARVATUD, KUID MITTE AINULT, MÜÜDAVUSE JA MINGIKS KINDLAKS OTSTARBEKS SOBIVUSE GARANTIID. BIOSENSE WEBSTER, INC. EGA SELLE SIDUSETTEVÕTTED EI VASTUTA ÜHELGI JUHUL KONKREETSETE, OTSESTE, JUHUSLIKE, PÕHJUSLIKE EGA MUUDE KAHJUDE EEST, VÄLJA ARVATUD KOHALDATAVATES ÕIGUSAKTIDES OTSESELT SÄTESTATUD JUHTUDEL.**

**BIOSENSE WEBSTER, INC. JA TEMA HARUFIRMAD EI OLE VASTUTAVAD MINGITE ERI, OTSESTE, KAUDSETE, TULENEVATE VÕI MUUDE KAHJUSTUSTE EEST, MIS ON TINGITUD ÜHEKORDSEKS KASUTAMISEKS MÕELDUD JA VASTAVALT TÄHISTATUD TOOTE KORDUVKASUTAMISEST VÕI KUI KORDUVKASUTAMINE ON KEHTIVA SEADUSANDLUSE ALUSEL KEELATUD.**

Firma Biosense Webster, Inc. trükistes avaldatavad kirjeldused ja spetsifikatsioonid, k.a. käesolev trükis, on informatiivse iseloomuga ja annavad üksnes toote üldkirjelduse, mis ei ole mingil juhul mõeldud andma tootele mingit garantiid.

## ELEKTROONILINE KASUTUSJUHEND

See dokument on kättesaadav aadressil www.e-ifu.com.

# TX *eco* -kaapeli

**Huomautus: Yhdysvaltain liittovaltion lain mukaan tämän laitteen saa myydä ainoastaan lisensoitu terveydenhuollon ammattilainen tai hänen määräyksestään.**

- Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut.

## LAITTEEN KUVAUS

TX *eco* -kaapelia käytetään jatkokaapelin kanssa Biosense Webster -hoitokatetrin yhdistämiseksi CARTO™ 3 -järjestelmän (versio 6 ja uudempi) potilaskäyttöliittymään (PIU). Jatkokaapelit on lueteltu alla:

- QDOT™-mikrokatetrille: TX *eco* EXT-kaapeli D135703
- muille Biosense Webster -hoitokatetreille: D128603 (luettelonumero CR3434CT) tai D128604 (luettelonumero CR3425CT)

TX *eco* -kaapeli välittää dataa Biosense Webster -hoitokatetrista CARTO™ 3 -järjestelmään ja radiotaajuusgeneraattoriin. Välitetyt tiedot on lueteltu alla.

- voimasignaalit
- sijaintisignaalit
- IC-signaalit kolmesta katetrin kärjessä olevasta mikroelektrodista (vain mikroelektrodeilla varustetut katetrit)
- lämpötilamittaukset kuudesta katetrin kärjessä olevasta lämpöparista

## KÄYTTÖAIHEET

TX *eco* -kaapelia käytetään yhdistämään Biosense Webster -hoitokatetri CARTO™ 3 -järjestelmän (versio 6 ja uudempi) potilaskäyttöliittymään (PIU).

## VAROITUKSET

1. Ennen tämän kaapelin käyttöä lue Biosense Webster -hoitokatetrin *käyttöohjeet*. Jos tätä kaapelia käytetään QDOT MICRO™ -moduulin kanssa, tutustu CARTO™ 3 -järjestelmän *käyttöohjeisiin* sekä QDOT MICRO™ -moduulin *käyttöohjeisiin ja julkaisutietoihin*, ennen kuin käytät tätä kaapelia QDOT MICRO™ -moduulin kanssa.
2. Vain sellainen henkilöstö, joka on lukenut ja sisäistänyt tämän asiakirjan sisällön, saa asentaa ja käyttää tätä kaapelia.
3. Tätä kaapelia saa käyttää vain Biosense Webster -hoitokatetrin kanssa. Älä kytke tätä kaapelia muihin katetreihin.
4. Kaapeli on tarkoitettu käytettäväksi ainoastaan Biosense Webster -hoitokatetrin, yhteensopivan radiotaajuusgeneraattorin, CARTO™ 3 -järjestelmän ja Biosense Webster -kaapeleiden kanssa. Kysy lisätietoja Biosense Webster -edustajalta.
5. Tämän kaapelin on oltava toimenpiteen aikana vähintään 1 m:n (39,4 in) etäisyydellä CARTO™ 3 -järjestelmän paikannuskehästä.
6. Tämä kaapeli on kytkettävä CARTO™ 3 -järjestelmän PIU:hun viideksi minuutiksi lämpenemään, jotta lämpötilalukemien tarkkuus varmistetaan. Lämpenemisjakson jälkeen lämpötilalukemat tasaantuvat. Jos kaapelia käytetään ennen lämpenemisjakson päättymistä, lämpötiloissa saattaa ilmetä vaihtelua.

## KAAPELIN ASENNUS JA KÄYTTÖ

### Kaapelin pidikkeen kiinnitys

1. Kiinnitä kaapelin pidikkeen kiristin (osanumero M652802) CARTO™ -järjestelmävaunun kahvaan tai toimenpidepöydän kiskoon. Kiristä sitten kaapelin pidikkeen nuppi.
2. Kiinnitä kaapeli pidikkeeseen siten, että kaapeli on alaspäin.

### Kaapelin kytkeminen

1. Kytke kaapelin punainen liitin CARTO™ 3 -järjestelmän PIU:ssa olevaan MAP-vastakkeeseen.
2. Kytke kaapelin keltainen liitin PIU:n QUAD B- tai DECA-vastakkeeseen.

   Huomautus 1: Molemmat liittimet on liitettävä PIU:hun.

   Huomautus 2: Liittimen kytkeminen QUAD A -vastakkeeseen voi aiheuttaa haitallista EKG-kohinaa.
3. Jos käytetään QDOT™-mikrokatetria, kytke katetri TX *eco* EXT -kaapelin toiseen päähän. Kytke TX *eco* EXT -kaapelin toinen pää TX *eco* -kaapelin päässä olevaan suureen liitäntään.
4. Jos käytät toista Biosense Webster -hoitokatetria, liitä katetri jatkokaapelin toiseen päähän. Kytke jatkokaapelin toinen pää TX *eco* -kaapelin päässä olevaan pienen pyöreään liitäntään.

### Kaapelin irrotus

1. Irrota punainen liitin CARTO™ 3 -järjestelmän PIU:sta vetämällä liitintä vapautuskytkimestä.
2. Irrota sitten keltainen liitin PIU:sta vetämällä liitintä vapautuskytkimestä.

   Huomautus: Molemmat liittimet on irrotettava PIU:sta. Älä jätä yhtä kaapelia kytketyksi ja toista irrotetuksi.
3. Kun olet irrottanut kaapelin, odota 10 sekuntia, ennen kuin kytket kaapelin uudelleen PIU:hun.

### LED-tila

LED-merkkivalo kertoo kaapelin tilan. Kun kaapeli on kytketty asianmukaisesti CARTO™ 3 -järjestelmän PIU:hun ja Biosense Webster -hoitokatetriin, kaapeli tekee itsetestin (BIT).

| LED | Kaapelin tila | Kommentit |
|---|---|---|
| Vihreä: vilkkuu hitaasti | Itsetestaus käynnissä | --- |
| Vihreä: palaa yhtäjaksoisesti | Valmis käyttöä varten | --- |
| Punainen: vilkkuu nopeasti | Virhe, itsetestaus epäonnistui | Lämpötiloja ei lähetetä CARTO™ 3 -järjestelmään tai radiotaajuusgeneraattoriin.<br>Katso *Vianmääritys*-osa tästä asiakirjasta. |

## KAAPELIN HUOLTO

### Puhdistus

Kaapelia ei tarvitse desinfioida tai steriloida. Älä höyrytä, autoklaavaa tai muutoin steriloi kaapelia.

Jos kaapelissa näkyy pölyä tai likaa, puhdista kaapeli seuraavalla tavalla:

1. Irrota kaapeli.
2. Puhdista kaapelin ulkopuoli pyyhkimällä se liinalla, joka on kostutettu alkoholittomalla käsisaippualla ja vedellä.
3. Varmista, ettei saippualiuosta pääse kaapelin liittimiin tai vastakkeisiin.
4. Varmista, että kaapeli on kuiva, ennen kuin kytket sen CARTO™ 3 -järjestelmään tai katetriin.

### Huolto

Kaapelissa ei ole käyttäjän huollettavissa olevia osia. Jos kaapeli menee epäkuntoon, ota yhteys asiakastukeen tai Biosense Webster -edustajaan vaihtoa varten. Kaapelin odotettu käyttöikä on kolme vuotta.

### Hävittäminen

Osat on kierrätettävä tai tuote ja sen jäännösosat tai jätteet hävitettävä paikallisten lakien ja säädösten mukaisesti.

## TEKNISET TIEDOT

### Tekniset tiedot

| | |
|---|---|
| **Tasavirtatulo** | Kaapeli saa virtaa CARTO™ 3 -järjestelmän PIU:sta. |
| **Paino** | 1 kg (2,2 lb) |
| **Mitat** | 10" pitkä x 1,9" leveä x 3" korkea<br>(254 mm x 48 mm x 76 mm) |
| **Lämpötilan tarkkuus** | ≤ 2 °C |

### Käyttö-, säilytys- ja kuljetustiedot

| | Minimi | Maksimi |
|---|---|---|
| **Käyttöohjearvot** | | |
| Ympäristön lämpötila | 10 °C | 30 °C |
| Suhteellinen kosteus* | 25 % | 75 % |
| **Säilytys- ja kuljetustiedot** | | |
| Ympäristön lämpötila | -30 °C | 65 °C |
| Suhteellinen kosteus* | 10 % | 95 % |

* MIL-STD-1695-standardin mukaan suhteellisen kosteuden on oltava 30–70 % paikoissa, joissa käsitellään elektronisia osia ja hybridimikropiirejä. MIL-STD-1695 edellyttää samantasoisia suhteellisen kosteuden säätimiä käsittely- ja varastointialueilla, paitsi jos tuotteet on peitetty tai suojattu.

### Sähkömagneettinen yhteensopivuus (EMC)

TX *eco* -kaapeli on tarkoitettu käytettäväksi sähkömagneettisissa ympäristöissä CARTO™ 3 -järjestelmän *käyttöohjeiden* mukaan.

## VIANMÄÄRITYS

Jos TX *eco* -kaapelin LED on punainen ja vilkkuu nopeasti, BIT on epäonnistunut ja aiheuttanut virheen (katso tämän asiakirjan osiota *LED-tila*). Noudata seuraavia vaiheita ongelman korjaamiseksi.

1. Irrota katetri kaapelista.
2. Irrota kaapeli CARTO™ 3 -järjestelmän PIU:sta.
3. Kiinnitä kaapeli uudestaan PIU:hun.
4. Kiinnitä katetri uudestaan kaapeliin.
5. Jos käytössä on QDOT MICRO™ -moduuli, noudata QDOT MICRO™ -moduulin *käyttöohjeita ja julkaisutietoja*.
6. Jos ongelma ei poistu, ota yhteys asiakastukeen tai Biosense Webster -edustajaan.

Joissain tilanteissa, kun laitteeseen kohdistuu 15 kV:n ilmapurkaus tai 8 kV:n kontaktipurkaus, CARTO™ 3 -järjestelmä näyttää samanaikaisesti 3 virheviestiä: Kartan pisteitä ei voi hakea (Virhe 401), Potilaan kehoviite on siirtynyt (Virhe 256) ja ponnahdusikkuna, joka ilmoittaa potilaan kehoviitteen muutoksen. Jos näin käy, käynnistä PIU uudelleen.

## TAKUUN VASTUUVAPAUTUSLAUSEKE JA VASTUUNRAJOITUS

**TÄSSÄ KUVATUILLE TUOTTEILLE EI OLE MITÄÄN ILMAISTUJA TAI HILJAISIA TAKUITA, MUKAAN LUKIEN RAJOITUKSITTA MIKÄ TAHANSA ILMAISTU TAKUU MYYNTIKELPOISUUDESTA TAI SOPIVUUDESTA JOHONKIN TIETTYYN TARKOITUKSEEN. BIOSENSE WEBSTER, INC. TAI SEN TYTÄRYHTIÖT EIVÄT MISSÄÄN TAPAUKSESSA OLE VASTUUSSA MISTÄÄN ERITYISISTÄ, SUORISTA TAI SATUNNAIS-, SEURANNAIS- TAI MUISTA VAHINGOISTA, PAITSI NIISTÄ, JOTKA OVAT NIMENOMAAN SOVELLETTAVAN LAIN ALAISIA.**

**RAJOITTAMATTA EDELLÄ OLEVAA, BIOSENSE WEBSTER, INC. TAI SEN SISARYHTIÖT EIVÄT OLE VASTUUSSA MISTÄÄN ERITYISISTÄ, SUORISTA, SATUNNAIS- TAI SEURANNAISVAHINGOISTA TAI MUISTA VAHINGOISTA, JOTKA AIHEUTUVAT MINKÄÄN SELLAISTEN TUOTTEIDEN UUDELLEENKÄYTÖSTÄ, JOTKA ON TEKSTEILLÄ MERKITTY KERTAKÄYTTÖISIKSI TAI MILLOIN UUDELLEEN KÄYTTÄMINEN ON SOVELLETTAVAN LAIN KIELTÄMÄÄ.**

Biosense Webster, Inc. -painotuotteissa esiintyvät kuvaukset ja tekniset tiedot, tämä julkaisu mukaan lukien, ovat ainoastaan tiedotusluonteisia ja tarkoitetut yksinomaan kuvaamaan yleisluontoisesti tuotetta sen valmistusajankohtana, eivätkä ole laadittu tai annettu millään tavoin määrätyn tuotteen takuuna.

## SÄHKÖISET KÄYTTÖOHJEET

Tämä asiakirja on saatavana osoitteesta www.e-ifu.com.

# Câble TX *eco*

**Attention : selon la loi fédérale américaine, cet appareil ne peut être vendu que par un professionnel de santé diplômé ou sur prescription médicale.**

- Ne pas utiliser si l'emballage est ouvert ou endommagé.

## DESCRIPTION DU DISPOSITIF

Le câble TX *eco* est utilisé avec une rallonge pour raccorder un cathéter thérapeutique Biosense Webster à l'unité d'interface patient (PIU) du système CARTO™ 3 (version 6 et ultérieures). Les rallonges sont répertoriées ci-dessous :

- Pour le cathéter QDOT™ Micro : câble TX *eco* EXT D135703
- Pour les autres cathéters thérapeutiques Biosense Webster : D128603 (référence CR3434CT) ou D128604 (référence CR3425CT)

Le câble TX *eco* communique les données du cathéter thérapeutique Biosense Webster au système CARTO™ 3 et au générateur RF. Les informations communiquées sont présentées ci-dessous.

- Signaux de force
- Signaux de localisation
- Signaux IC émis par les 3 microélectrodes qui se trouvent dans la pointe du cathéter (pour les cathéters dotés de microélectrodes uniquement)
- Mesures de température des 6 thermocouples qui se trouvent dans la pointe du cathéter

## INDICATIONS

Le câble TX *eco* est utilisé pour raccorder un cathéter thérapeutique Biosense Webster à l'unité d'interface patient (PIU) du système CARTO™ 3 (version 6 et ultérieures).

## AVERTISSEMENTS

1. Avant d'utiliser ce câble, lire le *mode d'emploi* du cathéter thérapeutique Biosense Webster. Si ce câble est utilisé avec le module QDOT MICRO™, se reporter au *mode d'emploi* du système CARTO™ 3, ainsi qu'au *mode d'emploi et aux notes de mise à jour* du module QDOT MICRO™ avant d'utiliser ce câble avec le module QDOT MICRO™.
2. Seul le personnel ayant lu et compris le contenu de ce document peut installer et utiliser ce câble.
3. Ce câble est validé uniquement pour une utilisation avec un cathéter thérapeutique Biosense Webster. Ne pas connecter ce câble à un autre cathéter.
4. Ce câble est destiné à être utilisé uniquement avec un cathéter thérapeutique Biosense Webster, un générateur RF compatible, un système CARTO™ 3 et les câbles Biosense Webster.Consulter le représentant de Biosense Webster pour plus d'informations.
5. Ce câble doit être installé à une distance minimale de 1 mètre (39,4 po) du pavé de localisation du système CARTO™ 3 pendant l'intervention.
6. Ce câble doit être raccordé à l'unité d'interface patient (PIU) du système CARTO™ 3 pendant une période de préchauffage de 5 minutes avant utilisation pour garantir l'exactitude des températures relevées. Après la période de préchauffage, les relevés de température se stabilisent. L'utilisation du câble avant la fin de la période de préchauffage peut provoquer une dérive de température.

## INSTALLATION ET UTILISATION DU CABLE

### Fixation du support de câble

1. Placer la partie de serrage du support de câble (référence M652802) du côté de la poignée du chariot du système CARTO™ ou sur le montant du lit. Serrer ensuite la molette sur le support de câble.
2. Insérer le câble dans le support de câble, en orientant le câble vers le bas.

### Branchement du câble

1. Raccorder le connecteur rouge du câble à la prise MAP de l'unité d'interface patient (PIU) du système CARTO™ 3.
2. Raccorder le connecteur jaune du câble à la prise QUAD B ou DECA de l'unité d'interface patient (PIU).

   Remarque 1 : les deux connecteurs doivent être branchés à l'unité d'interface patient (PIU).

   Remarque 2 : le raccordement du connecteur à la prise QUAD A peut entraîner un bruit indésirable de l'ECG.
3. En cas d'utilisation d'un cathéter QDOT™ Micro, raccorder le cathéter à une extrémité du câble TX *eco* EXT. Brancher l'autre extrémité du câble TX *eco* EXT à la grande prise située à l'extrémité du câble TX *eco*.
4. Si un autre cathéter thérapeutique Biosense Webster est utilisé, raccorder le cathéter à une extrémité de la rallonge. Brancher l'autre extrémité de la rallonge à la petite prise située à l'extrémité du câble TX *eco*.

### Débranchement du câble

1. Débrancher le connecteur rouge de l'unité d'interface patient (PIU) du système CARTO™ 3 en tirant sur le connecteur pour le dégager du dispositif de dégagement coulissant.
2. Débrancher ensuite le connecteur jaune de l'unité d'interface patient (PIU) en tirant sur le connecteur pour le dégager du dispositif de dégagement coulissant.

   Remarque : les deux connecteurs doivent être débranchés de l'unité d'interface patient (PIU). Ne pas laisser un câble branché et l'autre débranché.
3. Après avoir débranché le câble, patienter 10 secondes avant de reconnecter le câble à l'unité d'interface patient (PIU).

### État du voyant LED

L'état du câble est indiqué par un voyant LED. Une fois que le câble est correctement branché à l'unité d'interface patient (PIU) du système CARTO™ 3 et au cathéter thérapeutique Biosense Webster, il effectue un test intégré (BIT).

| LED | État du câble | Commentaires |
|---|---|---|
| Vert : clignote lentement | Test BIT en cours | --- |
| Vert : fixe | Prêt à l'emploi | --- |
| Rouge : clignote rapidement | Erreur, échec du test BIT | Les températures ne sont pas envoyées au système CARTO™ 3 ni au générateur RF.<br>Voir la section *Dépannage* dans ce document. |

## ENTRETIEN DU CABLE

### Nettoyage

Le câble ne nécessite ni désinfection, ni stérilisation. Ne pas stériliser le câble à la vapeur, ni en autoclave, ni d'aucune autre manière.

Si de la poussière ou des débris sont visibles sur le câble, le nettoyer comme suit :

1. Débrancher le câble.
2. Nettoyer l'extérieur du câble en l'essuyant avec un chiffon imbibé de savon liquide sans alcool et d'eau.
3. Veiller à ce qu'aucune solution savonneuse ne pénètre dans les connecteurs ou les prises du câble.
4. S'assurer que le câble est sec avant de le raccorder au système CARTO™ 3 ou à un cathéter.

### Entretien

Le câble ne comporte aucune pièce pouvant être réparée par l'utilisateur. Si le câble ne fonctionne pas, contacter le service d'assistance client ou le représentant de Biosense Webster pour demander son remplacement. La durée de vie utile prévue du câble est de trois ans.

### Mise au rebut

Recycler les composants ou éliminer le produit, ses éléments résiduels ou tout déchet conformément à la législation et aux réglementations locales.

## DONNEES TECHNIQUES

### Spécifications

| | |
|---|---|
| **Entrée CC** | Le câble est alimenté par l'unité d'interface patient (PIU) du système CARTO™ 3. |
| **Poids** | 1 kg (2,2 lb) |
| **Dimensions** | (10 po de long x 1,9 po de large x 3 po de haut)<br>(254 mm x 48 mm x 76 mm) |
| **Précision de la température** | ≤ 2 °C |

### Spécifications de fonctionnement, de stockage et d'expédition

| | Minimum | Maximum |
|---|---|---|
| **Caractéristiques de fonctionnement** | | |
| Température ambiante | 10 °C | 30 °C |
| Humidité relative* | 25 % | 75 % |
| **Spécifications de stockage et d'expédition** | | |
| Température ambiante | -30 °C | 65 °C |
| Humidité relative* | 10 % | 95 % |

* Conformément à la norme MIL-STD-1695, les taux d'humidité relative doivent se situer entre 30 % et 70 % dans les zones où les pièces électroniques et les microcircuits hybrides sont manipulés ou fabriqués. La norme MIL-STD-1695 exige le même niveau de contrôle de l'humidité relative pour les zones de manutention et de stockage, sauf si les composants sont couverts ou protégés.

### Informations en matière de CEM

Le câble TX *eco* est conçu pour être utilisé dans l'environnement électromagnétique décrit dans le *mode d'emploi* du système CARTO™ 3.

## DEPANNAGE

Si le voyant LED du câble TX *eco* est de couleur rouge et s'il clignote rapidement, cela signifie que le test BIT a échoué et qu'il a provoqué une erreur (voir la section *État du voyant LED* figurant dans ce document). Procéder comme décrit ci-dessous pour corriger le problème.

1. Débrancher le cathéter du câble.
2. Débrancher le câble de l'unité d'interface patient (PIU) du système CARTO™ 3.
3. Rebrancher le câble à l'unité d'interface patient (PIU).
4. Rebrancher le cathéter au câble.
5. Si un module QDOT MICRO™ est utilisé, suivre les instructions décrites dans le *mode d'emploi et les notes de mise à jour* du module QDOT MICRO™.
6. Si le problème persiste, contacter le service d'assistance client ou le représentant de Biosense Webster.

Dans certains cas où une décharge d'air de 15 kV ou une décharge de contact de 8 kV est appliquée au système, le système CARTO™ 3 affiche simultanément 3 messages d'erreur : Map points cannot be acquired (Acquisition des points de cartographie impossible) (Erreur 401), Patient Body Reference has moved (Déplacement de la référence du corps du patient) (Erreur 256), ainsi qu'un message contextuel indiquant un changement de la référence du corps du patient. Dans ce cas, redémarrer l'unité d'interface patient (PIU).

## DÉNI DE GARANTIES ET LIMITATION DE RESPONSABILITÉ

**LE OU LES PRODUITS DÉCRITS DANS LES PRÉSENTES NE SONT COUVERTS PAR AUCUNE GARANTIE EXPRESSE OU IMPLICITE, CECI INCLUANT, SANS S'Y LIMITER, TOUTE GARANTIE IMPLICITE DE QUALITÉ MARCHANDE OU D'ADAPTATION À UN USAGE PARTICULIER. EN AUCUN CAS BIOSENSE WEBSTER, INC. NE SERA TENUE RESPONSABLE DES DOMMAGES DIRECTS, INDIRECTS, CONSÉCUTIFS OU SPÉCIAUX, AUTRES QUE CEUX EXPRESSÉMENT PRÉVUS PAR LA LOI EN VIGUEUR.**

**SANS SE LIMITER À CE QUI PRÉCÈDE, BIOSENSE WEBSTER, INC. ET SES SOCIETÉS ASSOCIÉES, NE SERONT TENUES RESPONSABLES D'AUCUN DOMMAGE DIRECT, INDIRECT, CONSÉCUTIF OU SPÉCIAL PROVENANT DE LA RÉUTILISATION D'UN OU DES PRODUITS ÉTIQUETÉS POUR USAGE UNIQUE OU DONT LA RÉUTILISATION EST INTERDITE PAR LES LOIS APPLICABLES.**

Les descriptions et spécifications techniques figurant dans la documentation Biosense Webster, Inc., y compris cette publication, sont fournies à titre d'information et visent uniquement à décrire de façon générale le produit au moment de sa fabrication et ne constituent une garantie expresse en aucune manière.

## MODE D'EMPLOI ÉLECTRONIQUE

Ce document est disponible sur le site www.e-ifu.com.

# Kabel TX *eco*

**Oprez: Savezni zakon (SAD) ograničava prodaju ovog uređaja na licenciranog zdravstvenog djelatnika ili prema njegovom nalogu.**

- Proizvod nemojte koristiti ako je pakiranje otvoreno ili oštećeno.

## OPIS PROIZVODA

Kabel TX *eco* upotrebljava se s produžnim kabelom za povezivanje terapijskog katetera Biosense Webster s jedinicom za praćenje pacijenta (PIU) sustava CARTO™ 3 (verzija 6 i novija). Produžni kabeli navedeni su u nastavku:

- za mikrokateter QDOT™: kabel TX *eco* EXT D135703
- za druge terapijske katetere Biosense Webster: D128603 (kataloški br. CR3434CT) ili D128604 (kataloški br. CR3425CT)

Kabel TX *eco* prenosi podatke iz terapijskog katetera Biosense Webster u sustav CARTO™ 3 i RF generator. Informacije koje se prenose navedene su u nastavku.

- Signali sile pritiska
- Signali lokacije
- IC signali iz 3 mikroelektrode na vrhu katetera (samo za katetere s mikroelektrodama)
- Rezultati mjerenja temperature 6 termoparova na vrhu katetera

## INDIKACIJE ZA UPORABU

Kabel TX *eco* upotrebljava se za povezivanje terapijskog katetera Biosense Webster s jedinicom za praćenje pacijenta (PIU) sustava CARTO™ 3 (verzija 6 i novija).

## UPOZORENJA

1. Prije uporabe ovog kabela pročitajte *Upute za uporabu* terapijskog katetera Biosense Webster. Ako se kabel upotrebljava s modulom QDOT MICRO™, pročitajte *Upute za uporabu* sustava CARTO™ 3 te *Upute za uporabu i napomene uz izdanje* modula QDOT MICRO™ prije uporabe kabela s modulom QDOT MICRO™.
2. Ovaj kabel smiju postavljati i upotrebljavati isključivo zaposlenici koji su pročitali i razumjeli sadržaj ovog dokumenta.
3. Ovaj je kabel odobren za uporabu samo s terapijskim kateterom Biosense Webster. Nemojte priključivati ovaj kabel na druge vrste katetera.
4. Ovaj je kabel namijenjen za uporabu samo s terapijskim kateterom Biosense Webster, kompatibilnim RF generatorom, sustavom CARTO™ 3 i kabelima Biosense Webster. Obratite se predstavniku tvrtke Biosense Webster za pojedinosti.
5. Tijekom postupka kabel mora biti udaljen najmanje 1 metar (39,4 in) od lokacijskog podloška sustava CARTO™ 3.
6. Prije uporabe kabel mora biti povezan s PIU sustava CARTO™ 3 tijekom 5-minutnog razdoblja zagrijavanja kako bi se osiguralo točno očitanje temperature. Nakon razdoblja zagrijavanja stabilizirat će se očitanja temperature. Ako se kabel upotrebljava prije isteka razdoblja zagrijavanja, može doći do temperaturnog odstupanja.

## MONTAŽA I RAD S KABELOM

### Pričvršćivanje nosača kabela

1. Postavite stezaljku nosača kabela (broj dijela M652802) na bočnu stranu ručke kolica sustava CARTO™ ili preko ograde kreveta. Zatim zategnite gumb na nosaču kabela.
2. Umetnite kabel u nosač kabela tako da kabel bude okrenut prema dolje.

### Priključivanje kabela

1. Priključite crveni priključak kabela na utičnicu MAP na PIU sustava CARTO™ 3.
2. Priključite žuti priključak kabela na utičnicu QUAD B ili utičnicu DECA na PIU.

   Napomena 1: oba priključka moraju biti priključena na PIU.

   Napomena 2: priključivanje priključka na QUAD A može dovesti do nepoželjnih EKG šumova.
3. Ako upotrebljavate mikrokateter QDOT™, priključite kateter na jedan kraj kabela TX *eco* EXT. Priključite drugi kraj kabela TX *eco* EXT na veliku utičnicu na kraju kabela TX *eco*.
4. Ako upotrebljavate drugi terapijski kateter Biosense Webster, priključite kateter na jedan kraj produžnog kabela. Priključite drugi kraj produžnog kabela na malu okruglu utičnicu na kraju kabela TX *eco*.

### Iskopčavanje kabela

1. Iskopčajte crveni priključak iz PIU sustava CARTO™ 3 tako da povučete priključak iz kliznog drška.
2. Potom iskopčajte žuti priključak iz PIU tako da povučete priključak iz kliznog drška.

   Napomena: oba priključka moraju biti iskopčana iz PIU. Nemojte ostavljati jedan kabel priključenim, a drugi iskopčanim.
3. Nakon iskopčavanja kabela pričekajte 10 sekundi prije ponovnog priključivanja kabela u PIU.

### Status LED lampice

LED lampica označava status kabela. Nakon što se kabel pravilno priključi u PIU sustava CARTO™ 3 i na terapijski kateter Biosense Webster, kabel će provesti ugrađeno ispitivanje (BIT).

| LED | Status kabela | Napomene |
|---|---|---|
| Zelena: sporo treperi | BIT je u tijeku | --- |
| Zelena: postojano | Spremno za uporabu | --- |
| Crvena: brzo treperi | Pogreška, BIT nije uspio | Temperature se ne šalju u sustav CARTO™ 3 ili RF generator.<br>Pogledajte odjeljak *Otklanjanje poteškoća* u ovom dokumentu. |

## ODRŽAVANJE KABELA

### Čišćenje

Kabel nije potrebno dezinficirati niti sterilizirati. Nemojte sterilizirati kabel parom, u autoklavu ili na druge načine.

Ako se na kabelu pojavi prašina ili nečistoća, očistite kabel na sljedeći način:

1. Iskopčajte kabel.
2. Očistite vanjsku stranu kabela tako da ga obrišete krpom natopljenom u bezalkoholni sapun za ruke i vodu.
3. Pripazite da otopina sapuna ne uđe u kabelske priključke ili utičnice.
4. Provjerite je li kabel suh prije priključivanja na sustav CARTO™ 3 ili kateter.

### Održavanje

Ne postoje dijelovi kabela koje korisnik smije servisirati. Ako kabel ne radi, obratite se službi za korisnike ili predstavniku tvrtke Biosense Webster radi zamjene. Očekivani radni vijek kabela je tri godine.

### Zbrinjavanje

Komponente reciklirajte ili proizvod i njegove preostale ili otpadne dijelove zbrinite u skladu s lokalnim zakonima i propisima.

## TEHNIČKI PODACI

### Specifikacije

| | |
|---|---|
| **DC ulaz** | Kabel se napaja iz PIU sustava CARTO™ 3. |
| **Težina** | 1 kg (2,2 lb) |
| **Dimenzije** | dužina 10 in x širina 1,9 in x visina 3 in<br>(254 mm × 48 mm × 76 mm) |
| **Točnost temperature** | ≤ 2 °C |

### Specifikacije rada, skladištenja i transporta

| | Minimalno | Maksimalno |
|---|---|---|
| **Radne specifikacije** | | |
| Temperatura okoline | 10 °C | 30 °C |
| Relativna vlažnost* | 25 % | 75 % |
| **Specifikacije skladištenja i transporta** | | |
| Temperatura okoline | –30 °C | 65 °C |
| Relativna vlažnost* | 10 % | 95 % |

* U prostorima u kojima se obrađuju elektronički dijelovi i hibridni mikrosklopovi ili se rukuje njima, razina relativne vlažnosti prema standardu MIL-STD-1695 treba biti od 30 % do 70 %. Standard MIL-STD-1695 propisuje istu razinu relativne vlažnosti za prostore za rukovanje i skladištenje, osim kada su predmeti prekriveni ili zaštićeni.

### Informacije o elektromagnetskoj kompatibilnosti (EMC)

Kabel TX *eco* namijenjen je za uporabu u elektromagnetskom okruženju kako je navedeno u *Uputama za uporabu* sustava CARTO™ 3.

## OTKLANJANJE POTEŠKOĆA

Ako je LED lampica kabela TX *eco* crvene boje i brzo treperi, BIT nije bio uspješan što je dovelo do pogreške (pogledajte odjeljak *Status LED lampice* u ovom dokumentu). Slijedite korake u nastavku kako biste riješili problem.

1. Odvojite kateter od kabela.
2. Iskopčajte kabel iz PIU sustava CARTO™ 3.
3. Ponovno priključite kabel u PIU.
4. Ponovno priključite kateter u kabel.
5. Ako upotrebljavate modul QDOT MICRO™, pridržavajte se smjernica iz *Upute za uporabu i napomene uz izdanje* za modul QDOT MICRO™.
6. Ako se problem nastavi, obratite se službi za korisnike ili predstavniku tvrtke Biosense Webster.

U nekim situacijama, primjerice ako sustav primi pražnjenje zrakom od 15 kV ili pražnjenje kontaktom od 8 kV, sustav CARTO™ 3 prikazuje 3 poruke o pogreškama istovremeno: Map points cannot be acquired (Točke prikaza ne mogu se prikupljati) (pogreška 401), Patient Body Reference has moved (Tjelesna referenca pacijenta je pomaknuta) (pogreška 256) i skočni prozor s obavijesti o promjeni tjelesne reference pacijenta. Ako se to dogodi, ponovno pokrenite PIU.

## ODRICANJE OD JAMSTVA I OGRANIČENJE ODGOVORNOSTI

**NE POSTOJI JAMSTVO, EKSPLICITNO ILI IMPLICITNO, UKLJUČUJUĆI BEZ OGRANIČENJA BILO KOJE IMPLICITNO JAMSTVO UTRŽIVOSTI ILI PRIKLADNOSTI ZA ODREĐENU SVRHU U SVEZI S PROIZVODOM/PROIZVODIMA KOJI SU OVDJE OPISANI. BIOSENSE WEBSTER, INC. ILI NJEZINE PRIDRUŽENE TVRTKE NI POD KOJIM UVJETIMA NE MOGU BITI ODGOVORNE NI ZA KAKVU POSEBNU, IZRAVNU, SLUČAJNU, POSLJEDIČNU ILI NEKU DRUGU ŠTETU OSIM AKO TO NIJE IZRIČITO PROPISANO POSEBNIM ZAKONOM.**

**BEZ OGRANIČENJA GORE NAVEDENOGA, TVRTKA BIOSENSE WEBSTER, INC. ILI NJEZINE PODRUŽNICE NEĆE BITI ODGOVORNE NI ZA KAKVU POSEBNU, IZRAVNU, SLUČAJNU, POSLJEDIČNU ILI NEKU DRUGU ŠTETU NASTALU USLIJED PONOVNE UPORABE BILO KOJEG/KOJIH PROIZVODA OZNAČENOG/OZNAČENIH ZA JEDNOKRATNU UPORABU ILI GDJE JE PONOVNA UPORABA ZABRANJENA PRIMJENJIVIM ZAKONOM.**

Opisi i specifikacije koje se pojavljuju u tiskanim materijalima tvrtke Biosense Webster, Inc. uključujući i ovu publikaciju, informativnog su karaktera i isključivo su namijenjeni općem opisu proizvoda u trenutku njegove proizvodnje te ne pružaju niti na bilo koji način služe kao jamstvo za odnosni proizvod.

## ELEKTRONIČKE UPUTE ZA UPORABU

Ovaj dokument dostupan je na www.e-ifu.com.

# TX *eco* kábel

**Figyelem! Az Amerikai Egyesült Államok szövetségi törvényeinek értelmében az eszköz kizárólag engedéllyel rendelkező egészségügyi szakember által vagy ilyen szakember rendelvényére értékesíthető.**

- Tilos felhasználni, ha a csomagolás kinyílt vagy megsérült.

## ESZKÖZLEÍRÁS

A TX *eco* kábel hosszabbítókábellel használható Biosense Webster gyártmányú terápiás katéterek és a CARTO™ 3 rendszer (6-os és az annál újabb verziószámú ) páciensillesztő egységének (PIU) csatlakoztatására. A hosszabbítókábeleket az alábbiakban soroljuk fel:

- QDOT™ mikrokatéterhez: TX *eco* EXT kábel, D135703
- Egyéb Biosense Webster terápiás katéterekhez: D128603 (katalógusszám: CR3434CT) vagy D128604 (katalógusszám: CR3425CT)

A TX *eco* kábel adatokat továbbít Biosense Webster gyártmányú terápiás katéterekből a CARTO™ 3 rendszer és az RF-generátor felé. A továbbított információk felsorolása az alábbiakban olvasható.

- Erőjelek
- Elhelyezkedési jelek
- Intracardialis jelek a katéterhegyben található 3 mikroelektródból (kizárólag mikroelektródos katéterek esetében)
- Hőmérsékletmérések a katéterhegyben található 6 db termoelemből

## ALKALMAZÁSI TERÜLET

A TX *eco* kábel Biosense Webster gyártmányú terápiás katéterek és a CARTO™ 3 rendszer (6-os és az annál újabb verziószámú) páciensillesztő egységének (PIU) csatlakoztatására használható.

## FIGYELMEZTETÉSEK

1. A kábel használata előtt el kell olvasni a Biosense Webster terápiás katéter *használati utasítását*. Amennyiben a tárgyalt kábel felhasználása a QDOT MICRO™ modullal történik, ellenőrizni kell a CARTO™ 3 rendszer *használati utasítását*, valamint a QDOT MICRO™ modul *használati utasítását és kiadási megjegyzések* dokumentumát, mielőtt a kábelt a QDOT MICRO™ modullal használják.
2. A kábelt kizárólag olyan személy készítheti elő és használhatja, aki elolvasta és értelmezte a jelen dokumentumban foglaltakat.
3. A kábel kizárólag Biosense Webster gyártmányú terápiás katéterrel történő felhasználás tekintetében bevizsgált. A kábelt tilos bármilyen más katéterhez csatlakoztatni.
4. A kábel a rendeltetéséből adódóan kizárólag Biosense Webster terápiás katéterrel, kompatibilis RF-generátorral, a CARTO™ 3 rendszerrel és Biosense Webster gyártmányú kábelekkel együtt használható. A részletekkel kapcsolatban kérjen tanácsot a Biosense Webster képviseletétől.
5. A beavatkozás során a kábelt legalább 1 méter (39,4 col) távolságra kell tartani a CARTO™ 3 rendszer helyzetmeghatározó párnaelektródjától.
6. Használat előtt a kábelt a CARTO™ 3 rendszer PIU egységéhez kell csatlakoztatni 5 perces felmelegítés céljából, hogy biztosítani lehessen a hőmérsékletmérések pontosságát. A felmelegítési idő letelte után a hőmérséklet-értékek stabilizálódnak. Amennyiben a kábelt a felmelegítési idő vége előtt használják, a hőmérsékletértékek eltolódhatnak.

## A KÁBEL TELEPÍTÉSE ÉS ÜZEMELTETÉSE

### A kábeltartó felerősítése

1. Helyezze a kábeltartó szorítórészét (alkatrészszám: M652802) a CARTO™ rendszerhez tartozó kocsi fogantyújának oldalára vagy az ágykeretre. Ezután húzza szorosra a kábeltartón lévő rögzítőgombot.
2. Helyezze a kábelt a kábeltartóba úgy, hogy a kábel lefelé mutasson.

### A kábel csatlakoztatása

1. Csatlakoztassa a kábel piros csatlakozóját a CARTO™ 3 rendszer PIU-egységén található MAP bemenethez.
2. Csatlakoztassa a kábel sárga csatlakozóját a PIU-egységen található QUAD B vagy DECA bemenethez.

   1. megjegyzés: Mindkét csatlakozót csatlakoztatni kell a PIU-egységhez.

   2. megjegyzés: Ha a csatlakozót a QUAD A aljzathoz csatlakoztatják, nem kívánt EKG-zaj keletkezhet.
3. QDOT™ mikrokatéter használata esetén a katétert a TX *eco* EXT kábel egyik végéhez kell csatlakoztatni. A TX *eco* EXT kábel másik végét a TX *eco* kábel végén található nagy méretű aljzathoz kell csatlakoztatni.
4. Egyéb Biosense Webster gyártmányú terápiás katéter használata esetében a katétert a hosszabbítókábel egyik végéhez kell csatlakoztatni. Csatlakoztassa a hosszabbítókábel másik végét a TX *eco* kábel végén található kis kerek aljzathoz.

### A kábel leválasztása

1. A piros csatlakozó CARTO™ 3 rendszer PIU-egységéről történő leválasztásához húzza le a csatlakozót a csúsztatható kioldómarkolatról.
2. Ezután válassza le a sárga csatlakozót is a PIU-egységről úgy, hogy a csatlakozót lehúzza a csúsztatható kioldómarkolatról.

   Megjegyzés: Mindkét csatlakozót le kell választani a PIU-egységről. Tilos az egyik kábelt csatlakoztatva hagyni, ha a másik le van választva.
3. A kábel leválasztása után 10 másodpercet várni kell, mielőtt a kábelt ismét a PIU-egységhez csatlakoztatják.

### LED-es állapotjelzés

A kábel állapotát LED jelzi. Miután a kábelt megfelelően csatlakoztatták a CARTO™ 3 rendszer PIU-hoz és a Biosense Webster terápiás katéterhez, a kábel önellenőrzést végez.

| LED | A kábel állapota | Megjegyzések |
|---|---|---|
| Zöld: lassú villogás | Önellenőrzés folyamatban | --- |
| Zöld: folyamatos | Használatra kész | --- |
| Piros: szapora villogás | Hiba, az önellenőrzés sikertelen | A rendszer nem küld hőmérsékleti értékeket a CARTO™ 3 rendszerbe vagy az RF-generátorba.<br>Lásd a jelen dokumentumban található *Hibaelhárítás* című pontot. |

## A KÁBEL KARBANTARTÁSA

### Tisztítás

A kábel nem igényel fertőtlenítést vagy sterilizálást. A kábelt tilos gőzzel, autoklávban vagy más eljárással sterilizálni.

Amennyiben por vagy szennyeződés észlelhető a kábelen, az alábbiak szerint kell megtisztítani:

1. Válassza le a kábelt.
2. A kábel külsejének megtisztításához törölje át alkoholmentes kéziszappanos vízzel benedvesített kendővel.
3. Gondoskodjon róla, hogy a szappanos oldat ne kerüljön a kábel csatlakozóiba vagy aljzataiba.
4. Mielőtt a CARTO™ 3 rendszerhez vagy egy katéterhez csatlakoztatná, ellenőrizze, hogy megszáradt-e a kábel.

### Karbantartás

A kábelnek nincsenek a felhasználó által szervizelhető alkatrészei. Ha a kábel nem működik megfelelően, csere érdekében az ügyfélszolgálathoz vagy a Biosense Webster helyi képviseletéhez kell fordulni. A kábel tervezett hasznos élettartama három év.

### Ártalmatlanítás

Az alkotóelemeket újra kell hasznosítani, illetve a terméket és megmaradt elemeit vagy a használatából származó hulladékokat a helyi jogszabályok szerint kell ártalmatlanítani.

## MŰSZAKI ADATOK

### Műszaki adatok

| | |
|---|---|
| **Egyenáramú áramellátás** | A kábel áramellátását a CARTO™ 3 rendszer PIU-egysége biztosítja. |
| **Súly** | 1 kg (2,2 font) |
| **Méretek** | 10 col hosszú x 1,9 col széles x 3 col magas (254 mm x 48 mm x 76 mm) |
| **Hőmérséklet-pontosság** | ≤ 2 °C |

### Az üzemeltetés, tárolás és szállítás műszaki jellemző

| | Minimális | Maximális |
|---|---|---|
| **Üzemi specifikációk** | | |
| Környezeti hőmérséklet | 10 °C | 30 °C |
| Relatív páratartalom* | 25% | 75% |
| **Tárolási és szállítási specifikációk** | | |
| Környezeti hőmérséklet | –30 °C | 65 °C |
| Relatív páratartalom* | 10% | 95% |

* A MIL-STD-1695 szabvány előírásainak megfelelően a relatív páratartalomnak a 30% és 70% közötti tartományban kell lennie olyan helyeken, ahol elektronikus alkatrészeket és hibrid mikroáramköröket kezelnek vagy dolgoznak fel. A MIL-STD-1695 a relatív páratartalom azonos szabályozási szintjét írja elő kezelési és tárolási területekre is, kivéve, ha az eszközök le vannak fedve, vagy ha védve vannak.

### EMC-tudnivalók

A TX *eco* kábel a CARTO™ 3 rendszer *Használati utasításában* meghatározott elektromágneses környezetben történő alkalmazásra szánt eszköz.

## HIBAELHÁRÍTÁS

Ha a TX *eco* kábelen található LED piros fénnyel, szaporán villog, az önellenőrzés nem sikerült, és hibát okozott (lásd a jelen dokumentumban található *LED-es állapotjelzés* részt). A hiba korrigálásához az alábbi lépéseket kell követni.

1. Válassza le a katétert a kábelről.
2. Válassza le a kábelt a CARTO™ 3 rendszer PIU-egységéről.
3. Csatlakoztassa újra a kábelt a PIU-egységhez.
4. Csatlakoztassa újra a katétert a kábelhez.
5. QDOT MICRO™ modul használata esetén a QDOT MICRO™ modul *használati utasításában és kiadási megjegyzések* dokumentumában adott útmutatót kell követni.
6. Amennyiben a probléma továbbra is fennáll, az ügyfélszolgálathoz vagy a Biosense Webster helyi képviseletéhez kell fordulni.

Bizonyos helyzetekben, amikor 15 kV-os légköri vagy 8 kV-os érintkezési kisülés éri a rendszert, a CARTO™ 3 rendszer egyszerre 3 hibaüzenetet jelenít meg: „Map points cannot be acquired” (A térképpontok nem olvashatók be – 401-es hiba), „Patient Body Reference has moved” (A betegtest-referencia helyzete változott – 256-os hiba), valamint megjelenik egy felugró ablak a következő üzenettel: „Patient Body Reference change” (Betegtest-referencia megváltozott). Ebben az esetben újra kell indítani a PIU-egységet.

## A JÓTÁLLÁS KIZÁRÁSA ÉS A FELELŐSSÉG KORLÁTOZÁSA

**AZ ITT LEÍRT TERMÉK(EK)RE SEMMILYEN KIFEJEZETT VAGY BELEÉRTETT GARANCIA NEM ÉRVÉNYES, KORLÁTOZÁS NÉLKÜL IDEÉRTVE BÁRMILYEN, A FORGALOMBA HOZHATÓSÁGRA VONATKOZÓ BELEÉRTETT GARANCIÁT VAGY AZ ADOTT CÉLRA VALÓ ALKALMASSÁGOT. A BIOSENSE WEBSTER, INC. VAGY TÁRSULT CÉGEI A VONATKOZÓ TÖRVÉNYBEN KIMONDOTT ESETEN TÚL SEMMILYEN MÓDON NEM TEHETŐEK FELELŐSSÉ SEMMILYEN KÜLÖNLEGES, KÖZVETLEN, JÁRULÉKOS, KÖVETKEZMÉNYES VAGY EGYÉB KÁRÉRT.**

**A FENTIEK KORLÁTOZÁSA NÉLKÜL A BIOSENSE WEBSTER, INC. ÉS TÁRSULT CÉGEI NEM TEHETŐEK FELELŐSSÉ AZ EGYSZER HASZNÁLATOSKÉNT MEGJELÖLT TERMÉK(EK) TÖBBSZÖRI FELHASZNÁLÁSÁBÓL, VAGY A VONATKOZÓ TÖRVÉNNYEL ELLENTÉTES TÖBBSZÖRI FELHASZNÁLÁSBÓL EREDŐ SEMMILYEN KÜLÖNLEGES, KÖZVETLEN, JÁRULÉKOS, KÖVETKEZMÉNYES VAGY EGYÉB KÁRÉRT.**

A Biosense Webster, Inc. által kiadott nyomtatott anyagokban megjelenő ismertetések és leírások, jelen kiadványt is beleértve, kizárólag tájékoztató jellegűek, és a termék legyártáskori állapotának leírására szolgálnak, semmilyen értelemben nem tekinthetőek a leírt termékre vonatkozó garanciavállalásnak.

## ELEKTRONIKUS HASZNÁLATI UTASÍTÁS

Ez a dokumentum a következő webcímen érhető el: www.e-ifu.com.

# Kabel TX *eco*

**Perhatian: Hukum Federal (AS) membatasi alat ini untuk dijual oleh atau berdasarkan permintaan praktisi perawatan kesehatan berlisensi.**

- Jangan gunakan jika kemasan terbuka atau rusak.

## DESKRIPSI PERANGKAT

Kabel TX *eco* digunakan dengan perpanjangan kabel untuk menghubungkan kateter terapeutik Biosense Webster ke Satuan Antarmuka Pasien (PIU) dari Sistem CARTO™ 3 (Versi 6 dan yang lebih baru). Kabel perpanjangan tercantum di bawah ini:

- Untuk Kateter QDOT™ Micro: Kabel TX *eco* EXT D135703
- Untuk kateter terapeutik Biosense Webster lainnya: D128603 (katalog # CR3434CT) atau D128604 (katalog # CR3425CT)

Kabel TX *eco* menyampaikan data dari kateter terapeutik Biosense Webster ke Sistem CARTO™ 3 dan generator RF. Informasi yang disampaikan tercantum di bawah ini.

- Sinyal kekuatan
- Sinyal lokasi
- Sinyal IC dari 3 mikroelektrode di ujung kateter (untuk kateter dengan mikroelektrode saja)
- Pengukuran suhu dari 6 termokopel di ujung kateter

## INDIKASI PENGGUNAAN

Kabel TX *eco* digunakan untuk menghubungkan kateter terapeutik Biosense Webster ke Satuan Antarmuka Pasien (PIU) dari Sistem CARTO™ 3 (Versi 6 dan yang lebih baru).

## PERINGATAN

1. Sebelum menggunakan kabel ini, bacalah *Instruksi Penggunaan* untuk kateter terapeutik Biosense Webster. Jika kabel ini digunakan dengan Modul QDOT MICRO™, lihat *Instruksi Penggunaan* untuk Sistem CARTO™ 3 dan *Instruksi Penggunaan dan Catatan Rilis* untuk Modul QDOT MICRO™ sebelum menggunakan kabel ini dengan Modul QDOT MICRO™.
2. Hanya personel yang telah membaca dan memahami isi dokumen ini yang boleh memasang dan menggunakan kabel ini.
3. Kabel ini hanya divalidasi untuk penggunaan dengan kateter terapeutik Biosense Webster. Jangan menghubungkan kabel ini ke kateter lainnya.
4. Kabel ini dimaksudkan hanya untuk digunakan bersama kateter terapeutik Biosense Webster, generator RF yang kompatibel, Sistem CARTO™ 3, dan kabel Biosense Webster. Konsultasikan dengan perwakilan Biosense Webster Anda untuk detail selengkapnya.
5. Kabel ini harus berjarak minimal 1 meter (39,4 inci) dari bantalan lokasi Sistem CARTO™ 3 selama prosedur.
6. Kabel ini harus terhubung ke PIU Sistem CARTO™ 3 selama 5 menit untuk masa pemanasan sebelum digunakan untuk memastikan pembacaan suhu yang akurat. Setelah masa pemanasan, pembacaan suhu menjadi stabil. Jika kabel digunakan sebelum masa pemanasan selesai, mungkin terjadi pergeseran suhu.

## MEMASANG DAN MENGOPERASIKAN KABEL

### Memasang Pemegang Kabel

1. Tempatkan bagian klem dari pemegang kabel (nomor komponen M652802) pada sisi pegangan Troli Sistem CARTO™ atau di atas rel tempat tidur. Kemudian kencangkan tombol pada pemegang kabel.
2. Masukkan kabel ke dalam pemegang kabel dengan kabel menghadap ke bawah.

### Menghubungkan Kabel

1. Sambungkan konektor merah kabel ke soket MAP pada PIU Sistem CARTO™ 3.
2. Sambungkan konektor kuning kabel ke soket QUAD B atau DECA pada PIU.

   Catatan 1: Kedua konektor harus terhubung ke PIU.

   Catatan 2: Menghubungkan konektor ke QUAD A dapat menyebabkan kebisingan ECG yang tidak diinginkan.
3. Jika menggunakan Kateter QDOT™ Micro, hubungkan kateter ke salah satu ujung Kabel TX *eco* EXT. Hubungkan ujung Kabel TX *eco* EXT yang satunya ke soket besar di ujung Kabel TX *eco*.
4. Jika menggunakan kateter terapeutik Biosense Webster lainnya, hubungkan kateter ke salah satu ujung perpanjangan kabel. Hubungkan ujung lain dari kabel ekstensi ke soket bundar kecil di ujung Kabel TX *eco*.

### Melepas Kabel

1. Lepaskan konektor merah dari PIU Sistem CARTO™ 3 dengan menarik konektor dari pegangan pelepas geser.
2. Kemudian lepaskan konektor kuning dari PIU dengan menarik konektor dari pegangan pelepas geser.

   Catatan: Kedua konektor harus dilepaskan dari PIU. Jangan biarkan satu kabel terhubung sedangkan kabel yang satunya terlepas.
3. Setelah melepaskan kabel, tunggu 10 detik sebelum menghubungkan kembali kabel ke PIU.

### Status LED

Status kabel ditunjukkan oleh LED. Setelah kabel terhubung dengan benar ke PIU Sistem CARTO™ 3 dan ke kateter terapis Biosense Webster, kabel akan melakukan Pengujian Bawaan (BIT).

| LED | Status Kabel | Komentar |
|---|---|---|
| Hijau: berkedip lambat | BIT sedang berlangsung | --- |
| Hijau: terus menyala | Siap digunakan | --- |
| Merah: berkedip cepat | Kesalahan, BIT gagal | Suhu tidak dikirim ke Sistem CARTO™ 3 atau generator RF.<br>Lihat bagian *Penyelesaian Masalah* di dokumen ini. |

## PERAWATAN KABEL

### Pembersihan

Kabel tidak memerlukan desinfeksi atau sterilisasi. Jangan menguapi, mengautoklaf, atau mensterilkan kabel.

Jika debu atau serpihan muncul di kabel, bersihkan kabel dengan cara berikut:

1. Lepaskan kabel.
2. Bersihkan bagian luar kabel dengan menyekanya dengan lap yang dilembapkan dengan sabun tangan bebas alkohol dan air.
3. Pastikan tidak ada larutan sabun yang masuk ke konektor atau soket kabel.
4. Pastikan kabel kering sebelum menghubungkannya ke Sistem CARTO™ 3 atau ke kateter.

### Perawatan

Tidak ada bagian dalam kabel yang boleh diservis oleh pengguna. Jika kabel tidak dapat berfungsi, hubungi Dukungan Pelanggan atau perwakilan Biosense Webster Anda untuk mendapat penggantian. Perkiraan masa guna kabel adalah tiga tahun.

### Pembuangan

Daur ulang komponennya, atau buanglah produk beserta unsur sisa atau item limbahnya sesuai dengan undang-undang dan peraturan setempat.

## DATA TEKNIS

### Spesifikasi

| | |
|---|---|
| **Input DC** | Kabel menerima input daya dari PIU Sistem CARTO™ 3. |
| **Berat** | 1 kg (2,2 lb) |
| **Dimensi** | Panjang 10 inci x lebar 1,9 inci x tinggi 3 inci (254 mm x 48 mm x 76 mm) |
| **Akurasi Suhu** | ≤ 2 °C |

### Spesifikasi Pengoperasian, Penyampaian, dan Pengiriman

| | Minimum | Maksimum |
|---|---|---|
| **Spesifikasi Pengoperasian** | | |
| Suhu Ruang | 10 °C | 30 °C |
| Kelembapan relatif* | 25% | 75% |
| **Spesifikasi Penyimpanan dan Pengiriman** | | |
| Suhu Ruang | -30 °C | 65 °C |
| Kelembapan relatif* | 10% | 95% |

*Sesuai dengan MIL-STD-1695, tingkat kelembapan relatif harus berada dalam kisaran 30% hingga 70% di area tempat komponen elektronik dan mikrosirkuit hibrida ditangani atau diproses. MIL-STD-1695 mengharuskan tingkat kontrol kelembapan relatif yang sama untuk area penanganan dan penyimpanan, kecuali ketika item tertutup atau dilindungi.

### Informasi EMC

Kabel TX *eco* ditujukan untuk digunakan dalam lingkungan elektromagnetik sebagaimana ditentukan dalam *Instruksi Penggunaan* untuk Sistem CARTO™ 3.

## PEMECAHAN MASALAH

Jika LED pada Kabel TX *eco* berwarna merah dan berkedip cepat, BIT telah gagal dan telah menyebabkan kesalahan (lihat bagian *Status LED* di dokumen ini). Ikuti langkah-langkah di bawah ini untuk memperbaiki masalah.

1. Lepaskan kateter dari kabel.
2. Lepaskan kabel dari PIU Sistem CARTO™ 3.
3. Sambungkan kembali kabel ke PIU.
4. Sambungkan kembali kateter dari Kabel.
5. Jika Modul QDOT MICRO™ digunakan, ikuti petunjuk di *Instruksi Penggunaan Catatan Rilis* untuk Modul QDOT MICRO™.
6. Jika masalah tetap ada, hubungi Dukungan Pelanggan atau perwakilan Biosense Webster Anda.

Dalam beberapa situasi, ketika 15 kV luahan udara atau 8 kV luahan kontak diterapkan pada sistem, Sistem CARTO™ 3 menampilkan 3 pesan kesalahan secara bersamaan: Titik peta tidak dapat diperoleh (Galat 401), Referensi Tubuh Pasien telah berpindah (Galat 256), dan pesan sembulan yang menunjukkan perubahan Referensi Tubuh Pasien. Jika hal ini terjadi, mulai ulang PIU.

## DISCLAIMER GARANSI DAN BATAS KEWAJIBAN

**TIDAK ADA GARANSI SECARA TERSURAT MAUPUN TERSIRAT, TERMASUK NAMUN TIDAK TERBATAS PADA SEGALA GARANSI ATAS KONDISI YANG DAPAT DIPERDAGANGKAN DAN KESERASIAN UNTUK TUJUAN TERTENTU BERKAITAN DENGAN PENGGUNAAN PRODUK-PRODUK YANG DIURAIKAN DI SINI. BIOSENSE WEBSTER, INC., MAUPUN SEMUA PERUSAHAAN AFILIASINYA SAMA SEKALI TIDAK AKAN BERTANGGUNG JAWAB ATAS SEGALA KERUGIAN YANG BERSIFAT KHUSUS, LANGSUNG, TIDAK SENGAJA, MERUPAKAN AKIBAT, MAUPUN KERUGIAN LAIN YANG TIDAK DINYATAKAN SECARA TERSURAT OLEH HUKUM YANG BERLAKU.**

**TANPA MEMBATASI YANG TERDAHULU, BIOSENSE WEBSTER, INC. ATAU SEMUA PERUSAHAAN AFILIASINYA TIDAK AKAN BERTANGGUNG JAWAB ATAS SEGALA KERUGIAN YANG BERSIFAT KHUSUS, LANGSUNG, TIDAK SENGAJA, MERUPAKAN AKIBAT, MAUPUN KERUGIAN LAIN, YANG TERJADI AKIBAT PEMAKAIAN ULANG PRODUK APAPUN YANG BERTANDA SEKALI PAKAI ATAU DI MANA PEMAKAIAN ULANG DILARANG OLEH HUKUM YANG BERLAKU.**

Deskripsi dan spesifikasi yang terdapat pada barang cetakan Biosense Webster, Inc., termasuk publikasi ini, hanya bersifat informasi dan hanya bertujuan untuk menguraikan produk tersebut secara umum pada saat diproduksi dan sama sekali tidak dibuat atau diberikan sebagai garansi dari produk yang diuraikan.

## INSTRUKSI PENGGUNAAN ELEKTRONIK

Dokumen ini dapat dilihat di www.e-ifu.com.

# Cavo TX *eco*

**Attenzione: la legge federale degli Stati Uniti limita la vendita di questo dispositivo ai medici o dietro prescrizione medica di operatori sanitari abilitati.**

- Non utilizzare se la confezione è aperta o danneggiata.

## DESCRIZIONE DEL DISPOSITIVO

Il cavo TX *eco* si utilizza con un cavo di prolunga per collegare un catetere terapeutico Biosense Webster all'unità di interfaccia paziente (PIU) del sistema CARTO™ 3 (versione 6 e successive). I cavi di prolunga sono elencati di seguito:

- Per il catetere QDOT™ Micro: cavo TX *eco* EXT D135703
- Per altri cateteri terapeutici Biosense Webster: D128603 (n. di catalogo CR3434CT) o D128604 (n. di catalogo CR3425CT)

Il cavo TX *eco* trasmette i dati da un catetere terapeutico Biosense Webster al sistema CARTO™ 3 e al generatore RF. Le informazioni trasmesse sono elencate di seguito.

- Segnali di forza
- Segnali di posizione
- Segnali IC dai 3 microelettrodi presenti nella punta del catetere (solo per i cateteri con microelettrodi)
- Misure di temperatura dalle 6 termocoppie presenti nella punta del catetere

## INDICAZIONI PER L'USO

Il cavo TX *eco* si utilizza per collegare un catetere terapeutico Biosense Webster all'unità di interfaccia paziente (PIU) del sistema CARTO™ 3 (versione 6 e successive).

## AVVERTENZE

1. Prima di utilizzare il cavo, leggere le *Istruzioni per l'uso* del catetere terapeutico Biosense Webster. Se si utilizza il cavo con il modulo QDOT MICRO™, prima del suo utilizzo, fare riferimento alle *Istruzioni per l'uso* del sistema CARTO™ 3 e alle *Istruzioni per l'uso e alle Note di versione* del modulo QDOT MICRO™.
2. Solo il personale che ha letto e compreso il contenuto del presente documento può predisporre e utilizzare il cavo.
3. Il cavo è convalidato esclusivamente per l'uso con un catetere terapeutico Biosense Webster. Non connettere questo cavo ad altri cateteri.
4. Il cavo è indicato per l'uso esclusivo con un catetere terapeutico Biosense Webster, un generatore RF compatibile, un sistema CARTO™ 3 e i cavi Biosense Webster. Per i dettagli, rivolgersi al rappresentante Biosense Webster.
5. Durante la procedura, il cavo deve essere posizionato ad almeno 1 metro (39,4 in) di distanza dal location pad del sistema CARTO™ 3.
6. Il cavo deve rimanere collegato alla PIU del sistema CARTO™ 3 per un periodo di riscaldamento di 5 minuti prima dell'uso, al fine di assicurare letture di temperatura accurate. Dopo il periodo di riscaldamento, le letture di temperatura si stabilizzano. Se il cavo viene utilizzato prima della fine del periodo di riscaldamento, potrebbe verificarsi una deviazione delle temperature.

## INSTALLAZIONE E UTILIZZO DEL CAVO

### Installazione del porta cavo

1. Collocare il morsetto del porta cavo (codice prodotto M652802) sul lato della maniglia del carrello del sistema CARTO™ o sulla sponda del letto. Quindi stringere la manopola del porta cavo.
2. Inserire il cavo nel porta cavo con il cavo rivolto verso il basso.

### Collegamento del cavo

1. Collegare il connettore rosso del cavo all'ingresso MAP della PIU del sistema CARTO™ 3.
2. Collegare il connettore giallo del cavo all'ingresso QUAD B o DECA della PIU.

   Nota 1: entrambi i connettori devono essere collegati alla PIU.

   Nota 2: il collegamento del connettore all'ingresso QUAD A può comportare un rumore ECG indesiderato.
3. Se si utilizza un catetere QDOT™ Micro, collegare il catetere a un'estremità del cavo TX *eco* EXT. Collegare l'altra estremità del cavo TX *eco* EXT all'ingresso grande situato all'estremità del cavo TX *eco*.
4. Se si utilizza un altro catetere terapeutico Biosense Webster, collegare il catetere a un'estremità del cavo di prolunga. Collegare l'altra estremità del cavo di prolunga all'ingresso piccolo rotondo situato all'estremità del cavo TX *eco*.

### Scollegamento del cavo

1. Scollegare il connettore rosso dalla PIU del sistema CARTO™ 3 tirandolo dal dispositivo di presa con rilascio a scorrimento.
2. Quindi, scollegare il connettore giallo dalla PIU tirandolo dal dispositivo di presa con rilascio a scorrimento.

   Nota: entrambi i connettori devono essere scollegati dalla PIU. Non lasciare un cavo collegato e l'altro scollegato.
3. Dopo aver scollegato il cavo, attendere 10 secondi prima di ricollegarlo alla PIU.

### Stato del LED

Lo stato del cavo è indicato da una luce a LED. Dopo aver collegato correttamente il cavo alla PIU del sistema CARTO™ 3 e al catetere terapeutico Biosense Webster, il cavo esegue un test integrato (BIT).

| LED | Stato del cavo | Commenti |
|---|---|---|
| Verde: lento lampeggio | BIT in corso | --- |
| Verde: luce continua | Pronto per l'uso | --- |
| Rosso: rapido lampeggio | Errore, BIT non riuscito | Le temperature non vengono inviate al sistema CARTO™ 3 o al generatore RF.<br>Consultare la sezione *Risoluzione dei problemi* del presente documento. |

## CURA DEL CAVO

### Pulizia

Il cavo non richiede operazioni di disinfezione o sterilizzazione. Non sterilizzare il cavo a vapore, in autoclave o con altri metodi.

In presenza di polvere o detriti sul cavo, pulirlo attenendosi alla seguente procedura:

1. Scollegare il cavo.
2. Pulire la superficie esterna del cavo passandola con un panno inumidito con un detergente per mani privo di alcol e con acqua.
3. Accertarsi che la soluzione detergente non entri nei connettori o nelle prese del cavo.
4. Accertarsi che il cavo sia asciutto prima di collegarlo al sistema CARTO™ 3 o a un catetere.

### Manutenzione

Il cavo non contiene parti riparabili dall'utilizzatore. Se il cavo non funziona, rivolgersi all'Assistenza clienti o al rappresentante Biosense Webster per la sostituzione. La vita utile prevista del cavo è di tre anni.

### Smaltimento

Riciclare i componenti o smaltire il prodotto e i suoi elementi residui o i rifiuti in conformità con quanto previsto dalle normative e dalle legislazioni locali vigenti in materia.

## DATI TECNICI

### Specifiche

| | |
|---|---|
| **Alimentazione c.c.** | Il cavo riceve l'alimentazione elettrica dalla PIU del sistema CARTO™ 3. |
| **Peso** | 1 kg (2,2 lb) |
| **Dimensioni** | 10 in lunghezza × 1,9 in larghezza × 3 in altezza<br>(254 mm lunghezza × 48 mm larghezza × 76 mm altezza) |
| **Accuratezza della temperatura** | ≤ 2 °C |

### Specifiche di funzionamento, conservazione e trasporto

| | Minimo | Massimo |
|---|---|---|
| **Specifiche di funzionamento** | | |
| Temperatura ambiente | 10 °C | 30 °C |
| Umidità relativa* | 25% | 75% |
| **Specifiche di conservazione e trasporto** | | |
| Temperatura ambiente | -30 °C | 65 °C |
| Umidità relativa* | 10% | 95% |

* Ai sensi della norma MIL-STD-1695, i livelli di umidità relativa devono essere compresi nell'intervallo 30%-70% nelle aree in cui vengono manipolati o processati parti elettroniche o microcircuiti ibridi. La norma MIL-STD-1695 richiede lo stesso livello di controllo dell'umidità relativa nelle aree di manipolazione e conservazione, salvo quando i prodotti sono rivestiti o protetti.

### Informazioni sulla compatibilità elettromagnetica

Il cavo TX *eco* è destinato all'uso nell'ambiente elettromagnetico specificato nelle *Istruzioni per l'uso* del sistema CARTO™ 3.

## RISOLUZIONE DEI PROBLEMI

Se il LED sul cavo TX *eco* è rosso e lampeggia rapidamente, il test BIT non è andato a buon fine e ha causato un errore (vedere la sezione *Stato del LED* del presente documento). Attenersi alla seguente procedura per correggere il problema.

1. Scollegare il catetere dal cavo.
2. Scollegare il cavo dalla PIU del sistema CARTO™ 3.
3. Ricollegare il cavo alla PIU.
4. Ricollegare il catetere al cavo.
5. Se si utilizza un modulo QDOT MICRO™, seguire le istruzioni riportate nelle *Istruzioni per l'uso e nelle Note di versione* del modulo QDOT MICRO™.
6. Se il problema persiste, rivolgersi all'Assistenza clienti o al rappresentante locale Biosense Webster.

In alcune situazioni, quando sul sistema sono applicati 15 kV di scarica in aria o 8 kV di scarica di contatto, il sistema CARTO™ 3 visualizza contemporaneamente 3 messaggi di errore: Map points cannot be acquired (Impossibile acquisire punti sulla mappa, Errore 401), Patient Body Reference has moved (Il riferimento del corpo del paziente è stato spostato, Errore 256) e un pop-up che indica la modifica del riferimento relativo al paziente. In tal caso, riavviare la PIU.

## ESCLUSIONE DELLA GARANZIA E LIMITAZIONE DELLA RESPONSABILITÀ

**NON VIENE CONCESSA ALCUNA GARANZIA, ESPRESSA O TACITA, INCLUSE A TITOLO ESEMPLIFICATIVO E NON ESAUSTIVO GARANZIE TACITE DI COMMERCIABILITÀ O IDONEITÀ PER SCOPI PARTICOLARI SUI PRODOTTI DESCRITTI IN QUESTO DOCUMENTO. IN NESSUNA CIRCOSTANZA BIOSENSE WEBSTER, INC. O LE SOCIETÀ AD ESSA AFFILIATE POTRANNO ESSERE RITENUTE RESPONSABILI PER EVENTUALI DANNI SPECIALI, DIRETTI, ACCIDENTALI, CONSEGUENTI O DI ALTRA NATURA, CON L'ECCEZIONE DEI CASI ESPRESSAMENTE PREVISTI DA UNA SPECIFICA LEGGE.**

**FATTO SALVO QUANTO APPENA DICHIARATO, BIOSENSE WEBSTER, INC. O LE AZIENDE AD ESSA AFFILIATE NON POTRANNO ESSERE RITENUTE RESPONSABILI DI EVENTUALI DANNI SPECIALI, DIRETTI, INDIRETTI, CONSEGUENZIALI O DI EVENTUALI ALTRI DANNI, DERIVANTI DAL RIUTILIZZO DI PRODOTTI INDICATI COME MONOUSO O DI PRODOTTI IL CUI RIUTILIZZO È VIETATO DALLA LEGGE VIGENTE.**

Le descrizioni e le specifiche tecniche presentate nella documentazione Biosense Webster, Inc., inclusa la presente pubblicazione, sono da considerarsi esclusivamente informative e finalizzate a descrivere in maniera generale il prodotto al momento della realizzazione e non vanno intese in alcun modo come garanzia del prodotto prescritto.

## ISTRUZIONI PER L'USO ELETTRONICHE

Il documento è disponibile all'indirizzo www.e-ifu.com.

# TX *eco* 케이블

**주의: 연방법(미국)에 따라 본 장치의 판매는 면허가 있는 보건전문인이 직접 판매하거나 지시하 판매하는 경우로 제한됩니다.**

- 포장이 개봉되어 있거나, 손상된 경우 사용하지 마십시오.

## 장치 설명

TX *eco* 케이블은 연장 케이블과 함께 Biosense Webster 치료 카테터를 CARTO™ 3 시스템(버전 6 이상)의 환자 인터페이스 유닛(PIU)에 연결하는 데 사용됩니다. 연장 케이블은 다음과 같습니다.

- QDOT™ 마이크로 카테터의 경우: TX *eco* EXT 케이블 D135703
- 기타 Biosense Webster 치료 카테터의 경우: D128603(카탈로그 번호 CR3434CT) 또는 D128604(카탈로그 번호 CR3425CT)

TX *eco* 케이블은 Biosense Webster 치료 카테터에서 CARTO™ 3 시스템과 RF 제너레이터로 데이터를 전달합니다. 전달되는 정보는 아래와 같습니다.

- 힘 신호
- 위치 신호
- 카테터 팁에 위치한 마이크로 전극 3 개의 IC 신호(마이크로 전극이 있는 카테터만 해당)
- 카테터 팁에 위치한 열전쌍 6 개에서 측정된 온도

## 사용법

TX *eco* 케이블은 Biosense Webster 치료 카테터를 CARTO™ 3 시스템(버전 6 이상)의 환자 인터페이스 유닛(PIU)에 연결하는 데 사용됩니다.

## 경고

1. 케이블을 사용하기 전에, Biosense Webster 치료 카테터 *사용 설명서*를 읽으십시오. 만일 케이블을 QDOT MICRO™ 모듈과 함께 사용하고 있다면, QDOT MICRO™ 모듈과 케이블을 사용하기 전에 CARTO™ 3 시스템용 *사용 설명서* 및 QDOT MICRO™ 모듈용 *사용 설명서 및 릴리스 노트*를 참조하십시오.
2. 본 문서의 내용을 읽고 이해한 직원만이 해당 케이블을 설정하고 사용할 수 있습니다.
3. 본 케이블은 Biosense Webster 치료 카테터에만 사용하도록 검증되었습니다. 본 케이블을 기타 다른 카테터에 연결하지 마십시오.
4. 본 케이블은 Biosense Webster 치료 카테터, 호환 RF 제너레이터, CARTO™ 3 시스템, Biosense Webster 케이블에만 함께 사용해야 합니다. 자세한 사항은 Biosense Webster 담당자에 문의하십시오.
5. 케이블은 시술 중 CARTO™ 3 시스템의 위치 패드에서 반드시 1m(39.4in) 이상 떨어져 있어야 합니다.
6. 정확한 온도 판독을 보장하기 위해 케이블은 사용 전 반드시 5 분간 워밍업 시간 안 CARTO™ 3 시스템의 PIU 에 연결되어 있어야 합니다. 워밍업 시간 후에는 온도 판독값이 안정화됩니다. 워밍업 시간이 끝나기 전 케이블을 사용할 경우 온도 드리프트가 발생할 수 있습니다.

## 케이블 설치 및 작

### 케이블 홀더 부착

1. 케이블 홀더의 클램프 부분(부품 번호 M652802)을 CARTO™ 시스템 카트 핸들의 측면 또는 베드레일 위에 배치합니다. 그런 다음 케이블 홀더 위에 손잡이를 조입니다.
2. 케이블을 아래로 향하게 하여 케이블 홀더 안에 삽입합니다.

### 케이블 연결

1. 케이블의 빨간색 커넥터를 CARTO™ 3 시스템 PIU 의 MAP 소켓에 연결합니다.
2. 케이블의 노란색 커넥터를 PIU 의 QUAD B 또는 DECA 소켓에 연결합니다.

   참고 1: 반드시 커넥터 두 개 모두 PIU 에 연결되어야 합니다.

   참고 2: QUAD A 에 커넥터를 연결 시 불필요한 ECG 소음이 발생할 수 있습니다.
3. QDOT™ 마이크로 카테터를 사용하는 경우, 카테터를 TX *eco* EXT 케이블의 한 쪽 끝에 연결합니다. TX *eco* EXT 케이블의 다른 쪽 끝은 TX *eco* 케이블의 끝에 위치한 큰 소켓에 연결합니다.
4. 다른 Biosense Webster 치료 카테터를 사용하는 경우, 카테터를 연장 케이블의 한 쪽 끝에 연결합니다. 연장 케이블의 다른 쪽 끝은 TX *eco* 케이블의 끝에 위치한 작은 원형 소켓에 연결합니다.

### 케이블 분리

1. 빨간색 커넥터를 슬라이드 릴리스 그립에서 당겨 CARTO™ 3 시스템 PIU 에서 커넥터를 분리합니다.
2. 그 다음 노란색 커넥터를 슬라이드 릴리스 그립에서 당겨 PIU 에서 커넥터를 분리합니다.

   참고: 반드시 커넥터 두 개 모두 PIU 에 분리되어야 합니다. 둘 중 하나의 케이블만 연결된 채로 두지 마십시오.
3. 케이블을 분리한 뒤, PIU 에 케이블 재연결하려면 10 초를 기다린 후 진행합니다.

### LED 상태

케이블의 상태는 LED 로 표시됩니다. 케이블이 CARTO™ 3 시스템 PIU 및 Biosense Webster 치료용 카테터에 적절히 연결되면, 케이블이 장착 테스트(BIT)를 수행합니다.

| LED | 케이블 상태 | 설명 |
|---|---|---|
| 초록색: 느리게 점멸 | BIT 진행 중 | --- |
| 초록색: 정지 | 사용 가능 | --- |
| 빨간색: 빠르게 점멸 | 오류, BIT 실패 | 온도 정보가 CARTO™ 3 시스템 또는 RF 제너레이터에 전달되지 않았습니다.<br>이 문서의 *문제해결* 섹션을 참조하십시오. |

## 케이블 관리

### 세척

케이블은 살균 또는 멸균이 필요하지 않습니다. 증기 살균, 고압 살균, 또는 기타 다른 방법으로 케이블을 멸균하지 마십시오.

먼지나 이물질이 케이블에 보일 경우, 다음의 방법으로 청소하십시오.

1. 케이블을 분리합니다.
2. 케이블의 바깥쪽은 무알코올 손 세정제와 물로 적신 천을 사용해 닦아 깨끗이 합니다.
3. 비누 용액이 케이블 커넥터나 소켓에 미량이라도 들어가지 않도록 주의합니다.
4. 케이블을 CARTO™ 3 시스템이나 카테터에 연결하기 전 케이블이 건조되어 있는지 확인합니다.

### 유지 관리

케이블에는 사용자가 정비할 수 있는 부품이 없습니다. 케이블이 작동하지 않는다면, 고객 지원 부서 또는 Biosense Webster 대리점에 연락하여 교체를 문의하십시오. 케이블의 기대 사용 수명은 3 년입니다.

### 폐기

부품을 재활용하거나 제품 및 제품의 나머지 구성품 또는 폐기물은 해당 지역 법 및 규정에 따라 폐기하십시오.

## 기술 데이터

### 사양

| | |
|---|---|
| **DC 입력** | 케이블은 CARTO™ 3 시스템의 PIU 에서 전원을 입력 받습니다. |
| **무게** | 1kg(2.2lb) |
| **치수** | 길이 10in x 너비 1.9in x 높이 3in<br>(254mm x 48mm x 76mm) |
| **온도 정확도** | ≤ 2°C |

### 작 , 보관, 운송 사양

| | 최소 | 최대 |
|---|---|---|
| **작 사양** | | |
| 주변 온도 | 10°C | 30°C |
| 상대 습도* | 25% | 75% |
| **보관 및 운송 사양** | | |
| 주변 온도 | -30°C | 65°C |
| 상대 습도* | 10% | 95% |

* MIL-STD-1695 에 따라 전기 부품 및 하이브리드 마이크로회로를 취급하거나 처리하는 장소의 상대습도 수준은 30% ~ 70% 이내여야 합니다. MIL-STD-1695 에서는 물품이 싸여 있거나 보호되지 않는 이상 취급 및 보관 장소에도 동일한 수준의 상대 습도 관리를 요구합니다.

### EMC 정보

TX *eco* 케이블은 CARTO™ 3 시스템 *사용 설명서*에 명시되어 있는 것과 같이 전자파 환경에서 사용되도록 제작되었습니다.

## 문제해결

TX *eco* 케이블 위 LED 가 빨간색으로 빠르게 깜빡일 경우, BIT 가 실패하여 오류가 발생한 것입니다(이 문서의 ***LED 상태*** 참조). 문제를 해결하려면 아래 절차를 따르십시오.

1. 케이블을 카테터에서 분리합니다.
2. 케이블을 CARTO™ 3 시스템 PIU 에서 분리합니다.
3. 케이블을 PIU 에 다시 연결합니다.
4. 카테터를 케이블에 다시 연결합니다.
5. QDOT MICRO™ 모듈을 사용하는 경우, QDOT MICRO™ 모듈용 *사용 설명서 및 릴리스 노트*를 따르십시오.
6. 문제가 지속된다면, 고객 지원 부서 또는 Biosense Webster 대리점에 문의하십시오.

CARTO™ 3 시스템은 15 kV 의 공기 방전 또는 8 kV 의 접촉 방전이 시스템에 적용되는 경우 '맵 포인트를 획득할 수 없습니다(오류 401)', '환자 신체 범위 위치가 변경되었습니다(오류 256)', '환자 신체 범위 변경을 나타내는 팝업 메시지가 표시됩니다'라는 3 개의 오류 메시지를 동시 표시합니다. 이와 같은 상황이 발생할 경우, PIU 를 다시 시작하십시오.

## 보증 및 책임 제한

**본 자료에 서술된 제품에 대해서는 상품성 또는 특정 용도 적합성에 대한 묵시적 하자보증을 비롯하 일체의 명시적 또는 묵시적 하자보증이 없습니다. 어떤 경우에도 BIOSENSE WEBSTER, INC.나 계열 회사는 적용 가능한 법에 의해 명시적으로 규정되지 않은 특별적, 직접적, 부수적, 결과적 또는 기타 피해에 대해 책임을 지지 않습니다.**

**전기 사항에 대한 제한 없이, BIOSENSE WEBSTER, INC.나 계열 회사는 일회용으로 표시되거나 또는 해당 법에 의해 재사용이 금지된 경우에 제품을 재사용한데서 비롯된 특별적, 직접적, 부수적, 결과적 또는 기타 피해에 대해 책임이 없습니다.**

본 간행물을 비롯하여 Biosense Webster, Inc. 유인물에 나타나는 설명과 사양은 단지 안내용이며 제조 당시 제품을 일반적으로 서술하기 위한 것뿐이며 어떤 식으로든 명시된 제품에 대한 하자보증으로 제공되는 것이 아닙니다.

## 전자기기 사용 설명서

이 문서는 www.e-ifu.com 에서 입수할 수 있습니다.

# Kabelis „TX *eco*“

**Įspėjimas. Pagal federalinius (JAV) įstatymus šį prietaisą galima parduoti arba užsakyti tik licencijuotam sveikatos priežiūros specialistui.**

- Nenaudoti, jei pakuotė atidaryta ar pažeista.

## PRIETAISO APRAŠYMAS

Kabelis „TX *eco*“ yra naudojamas kartu su ilginamuoju kabeliu prijungti „Biosense Webster“ terapinį kateterį prie CARTO™ 3 sistemos paciento sąsajos įrenginio (angl. k. PIU) (6 versija ir vėlesnė). Ilginamųjų kabelių sąrašas pateiktas toliau:

- „QDOT™ Micro“ kateteriui: kabelis „TX *eco* EXT“ D135703;
- kitiems „Biosense Webster“ terapiniams kateteriams: D128603 (katalogo Nr. CR3434CT) arba D128604 (katalogo Nr. CR3425CT).

Kabelis „TX *eco*“ perduoda duomenis iš „Biosense Webster“ terapinio kateterio į CARTO™ 3 sistemą ir radijo dažnių generatorių. Perduodama informacija pateikiama toliau:

- priverstiniai signalai;
- vietos signalai;
- informacija, perduodama iš 3 kateterio viršūnėje esančių mikroelektrodų (tik kateteriams su mikroelektrodais);
- temperatūros matavimai, atliekami iš 6 termoporų, esančių kateterio viršūnėje.

## NAUDOJIMO INDIKACIJOS

Kabelis „TX *eco*“ yra naudojamas prijungti „Biosense Webster“ terapinį kateterį prie CARTO™ 3 sistemos paciento sąsajos įrenginio (angl. k. PIU) (6 versija ir vėlesnė).

## ĮSP JIMAI

1. Prieš naudodami kabelį, perskaitykite „Biosense Webster“ terapinio kateterio *naudojimo instrukciją*. Jei kabelis naudojamas su QDOT MICRO™ moduliu, prieš naudodami šį kabelį su QDOT MICRO™ moduliu, perskaitykite CARTO™ 3 sistemos *naudojimo instrukciją* ir QDOT MICRO™ modulio *naudojimo instrukciją ir laidos informaciją*.
2. Kabelį pajungti ir naudoti gali tik darbuotojai, kurie perskaitė ir suprato šio dokumento turinį.
3. Kabelis yra patvirtintas naudoti tik su „Biosense Webster“ terapiniu kateteriu. Nejunkite šio kabelio prie jokio kito kateterio.
4. Šis kabelis yra skirtas naudoti tik su „Biosense Webster“ terapiniu kateteriu, suderinamu RD generatoriumi, CARTO™ 3 sistema ir „Biosense Webster“ kabeliais. Jei reikia daugiau informacijos, susisiekite su „Biosense Webster“ atstovu.
5. Procedūros metu kabelis turi būti mažiausiai 1 metro (39,4 col.) atstumu nuo CARTO™ 3 sistemos vietos padėklo.
6. Prieš naudojimą 5 minutėms kabelis turi būti prijungtas prie CARTO™ 3 sistemos PIU, kad įšiltų ir kad būtų užtikrintas tikslus temperatūros rodmuo. Praėjus įšilimo laikotarpiui, temperatūros rodmenys stabilizuojasi. Jei kabelis naudojamas prieš pasibaigiant įšilimo laikotarpiui, gali įvykti temperatūros slinkis.

## KABELIO ĮRENGIMAS IR NAUDOJIMAS

### Kabelio laikiklio tvirtinimas

1. Kabelio laikiklio spaustuko dalį (dalies numeris M652802) uždėkite ant CARTO™ sistemos vežimėlio rankenos arba virš lovos turėklo. Tuomet priveržkite ranken , esančią ant kabelio laikiklio.
2. Įkiškite kabelį į kabelio laikiklį (kabelis nukreiptas žemyn).

### Kabelio prijungimas

1. Prijunkite raudoną laido jungtį prie MAP lizdo, esančio CARTO™ 3 sistemos PIU.
2. Prijunkite geltoną laido jungtį prie PIU lizdo QUAD B arba DECA.

   1 pastaba. Abi jungtys turi būti prijungtos prie PIU.

   2 pastaba. Prijungus jungtį prie QUAD A, gali atsirasti nepageidaujamas EKG triukšmas.
3. Jei naudojate „QDOT™ Micro“ kateterį, prijunkite kateterį prie vieno „TX *eco* EXT“ kabelio galo. Įjunkite kitą „TX *eco* EXT“ kabelio galą į lizdą, esantį „TX *eco*“ kabelio gale.
4. Jei naudojate kitą „Biosense Webster“ terapinį kateterį, prijunkite kateterį prie vieno ilginamojo kabelio galo. Įjunkite kitą ilginamojo kabelio galą į mažą apvalų lizdą, esantį „TX *eco*“ kabelio gale.

### Kabelio atjungimas

1. Atjunkite raudoną jungtį nuo CARTO™ 3 sistemos PIU, patraukdami jungtį už slankiojamosios atleidimo rankenos.
2. Tada atjunkite geltoną jungtį nuo PIU, patraukdami jungtį už slankiojamosios atleidimo rankenos.

   Pastaba. Abi jungtys turi būti atjungtos nuo PIU. Nepalikite vieno kabelio prijungto, o kito atjungto.
3. Atjung kabelį, palaukite 10 sekundžių prieš pakartotinai prijungdami kabelį prie PIU.

### Šviesos diodo būsena

Kabelio būseną rodo šviesos diodas. Kai kabelis tinkamai prijungtas prie CARTO™ 3 sistemos PIU ir prie „Biosense Webster“ terapinio kateterio, kabelis atlieka integravimo patikrinimą (angl. k. BIT).

| Šviesos diodas | Kabelio būsena | Pastabos |
|---|---|---|
| Žalia: lėtai mirksi | Vykdomas BIT | --- |
| Žalia: šviečia tolygiai | Pasireng s | --- |
| Raudona: greitai mirksi | Klaida, BIT nepavyko | Temperatūra nesiunčiama į CARTO™ 3 sistemą ar RD generatorių.<br>Žr. šio dokumento skyrių „*Trikčių šalinimas*“. |

## KABELIO PRIEŽIŪRA

### Valymas

Kabelio nereikia dezinfekuoti ar sterilizuoti. Nesterilizuokite kabelio garais, autoklave arba kitaip.

Jei ant kabelio atsiranda dulkių arba nešvarumų, valykite jį taip, kaip nurodyta toliau.

1. Atjunkite kabelį.
2. Kabelio išor valykite drėgna šluoste, suvilgyta rankų muilu be alkoholio ir vandeniu.
3. Įsitikinkite, kad muilo tirpalo nepateks į kabelio jungtis arba lizdus.
4. Prieš prijungdami laidą prie CARTO™ 3 sistemos ar kateterio, įsitikinkite, kad jis yra sausas.

### Techninė priežiūra

Kabelyje nėra dalių, kurias galėtų prižiūrėti naudotojas. Jei kabelis neveikia tinkamai, kreipkitės į klientų aptarnavimo skyrių arba savo „Biosense Webster“ atstovą bei gaukite pakaitinį kabelį. Tikėtina kabelio naudojimo trukmė yra treji metai.

### Utilizavimas

Komponentus perdirbkite arba gaminį ir jo likusias dalis ar atliekas utilizuokite pagal vietos įstatymus ir kitus teisės aktus.

## TECHNINIAI DUOMENYS

### Specifikacijos

| | |
|---|---|
| **Nuolatinės srovės įvestis** | Kabelis gauna energiją iš CARTO™ 3 sistemos PIU. |
| **Svoris** | 1 kg (2,2 sv.) |
| **Matmenys** | 10 col. ilgio x 1,9 col. pločio x 3 col. aukščio (254 mm x 48 mm x 76 mm) |
| **Temperatūros tikslumas** | ≤ 2 °C |

### Eksploatavimo, laikymo ir gabenimo specifikacijos

| | Mažiausia | Daugiausia |
|---|---|---|
| **Darbo aplinkos specifikacijos** | | |
| Aplinkos temperatūra | 10 °C | 30 °C |
| Santykinis drėgnis* | 25 % | 75 % |
| **Laikymo ir gabenimo specifikacijos** | | |
| Aplinkos temperatūra | –30 °C | 65 °C |
| Santykinis drėgnis* | 10 % | 95 % |

* Pagal MIL-STD-1695, santykinės drėgmės lygis turi būti nuo 30 % iki 70 % tose vietose, kur yra tvarkomos ar apdorojamos elektroninės dalys ir hibridinės mikroschemos. Pagal MIL-STD-1695 tokį patį drėgnio lygį reikalaujama užtikrinti tvarkymo bei laikymo srityse, išskyrus atvejus, kai įranga yra uždengta arba apsaugota.

### EMS informacija

„TX *eco*“ kabelis yra skirtas naudoti elektromagnetinėje aplinkoje, kaip nurodyta CARTO™ 3 sistemos *naudojimo instrukcijoje*.

## TRIKČIŲ ŠALINIMAS

Jei „TX *eco*“ kabelio šviesos diodas dega raudonai ir greitai mirksi, vadinasi BIT nepavyko ir sukėlė klaidą (žr. šio dokumento skyrių *„Šviesos diodo būsena“)*. Norėdami pašalinti problemą, atlikite toliau nurodytus veiksmus.

1. Atjunkite kateterį nuo kabelio.
2. Atjunkite laidą nuo CARTO™ 3 sistemos PIU.
3. Pakartotinai prijunkite kabelį prie PIU.
4. Pakartotinai prijunkite kateterį prie kabelio.
5. Jei naudojamas QDOT MICRO™ modulis, vykdykite nurodymus, pateiktus QDOT MICRO™ modulio *naudojimo instrukcijoje ir laidos informacijoje*.
6. Jei problema išlieka, susisiekite su klientų aptarnavimo skyriumi arba savo „Biosense Webster“ atstovu.

Kai kuriose situacijose, sistemoje esant 15 kV orinio išlydžio įtampai arba 8 kV kontaktinio išlydžio įtampai, CARTO™ 3 sistema vienu metu rodo 3 klaidos pranešimus kartu: „Map points cannot be acquired“ (Atvaizdo taškų gauti negalima) (401 klaida), „Patient Body Reference has moved“ (Paciento kūnas pajudėjo) (256 klaida), ir iššokantis pranešimas, rodantis paciento padėties pasikeitimą. Jei taip nutiktų, pakartotinai paleiskite PIU.

## ATSISAKYMAS SUTEIKTI GARANTIJĄ IR ATSAKOMYB S RIBOJIMAS

**ČIA APIBŪDINTAM (-IEMS) PRODUKTUI (-AMS) TIKSLIOS IR NUMANOMOS GARANTIJOS N RA, BE APRIBOJIMŲ ĮSKAITANT BET KOKIĄ NUMANOMĄ PARDAVIMO GARANTIJĄ AR JOS PRITAIKYMĄ KONKREČIU ATVEJU. „BIOSENSE WEBSTER, INC.“ AR JOS DUKTERIN S BENDROV S JOKIOMIS APLINKYB MIS NEATSAKO UŽ JOKIĄ KONKREČIĄ, TIESIOGIN , ATSITIKTIN , PASEKMIN AR KITOKIĄ ŽALĄ, IŠSKYRUS AIŠKIAI NURODYTĄ TAIKOMUOSE ĮSTATYMUOSE.**

**„BIOSENSE WEBSTER, INC.“ AR JOS DUKTERIN S KOMPANIJOS NERIBOJANT AUKŠČIAU PAMIN TŲ ATVEJŲ N RA ATSAKINGA UŽ JOKIUS TYČINIUS, TIESIOGINIUS, ATSITIKTINIUS, PASEKMINIUS AR KITOKIUS PAŽEIDIMUS, KYLANČIUS D L PAKARTOTINIO PRODUKTO (-Ų) NAUDOJIMO, KURIE BUVO PAŽYM TI KAIP VIENKARTINIO NAUDOJIMO ARBA KURĮ PAKARTOTINAI NAUDOTI DRAUDŽIA ATITINKAMI ĮSTATYMAI.**

„Biosense Webster, Inc.“ spausdintoje medžiagoje pateikiami aprašymai ir specifikacijos tai tik informacija ir joje tik bendrais bruožais aprašomas produktas gaminimo metu ir tai jokiu būdu nėra nurodyto produkto garantija.

## ELEKTRONIN S NAUDOJIMO INSTRUKCIJOS

Šį dokumentą galima rasti adresu www.e-ifu.com.

# TX *eco* kabelis

**Uzmanību: ASV federālie likumi ļauj šo ierīci tirgot tikai veselības aprūpes speciālistiem vai pēc veselības aprūpes speciālistu norādījuma.**

- Neizmantot, ja iepakojums ir atvērts vai bojāts.

## IERĪCES APRAKSTS

TX *eco* kabeli lieto kopā ar pagarinātāja kabeli, lai Biosense Webster terapeitisko katetru savienotu ar CARTO™ 3 sistēmas (6. vai jaunākas versijas) pacienta saskarnes ierīci (PSI). Pagarinātāja kabeļi ir norādīti turpinājumā.

- QDOT™ mikrokatetram: TX *eco* EXT kabelis D135703
- Citiem Biosense Webster terapeitiskajiem katetriem: D128603 (kataloga Nr. CR3434CT) vai D128604 (kataloga Nr. CR3425CT)

Izmantojot TX *eco* kabeli, Biosense Webster terapeitiskā katetra dati tiek pārraidīti uz CARTO™ 3 sistēmu un RF ģeneratoru. Pārraidītā informācija ir norādīta tālāk.

- Pārraides spēka signāli
- Atrašanās vietas signāli
- IC signāli no 3 mikroelektrodiem katetra uzgalī (tikai katetriem ar mikroelektrodiem)
- Temperatūras mērījumi no 6 termoelementiem katetra uzgalī

## LIETOŠANAS INDIKĀCIJAS

TX *eco* kabeli lieto, lai Biosense Webster terapeitisko katetru savienotu ar CARTO™ 3 sistēmas (6. vai jaunākas versijas) pacienta saskarnes ierīci (PSI).

## BRĪDINĀJUMI

1. Pirms šī kabeļa lietošanas izlasiet Biosense Webster terapeitiskā katetra dokumentu *Lietošanas norādījumi*. Ja šis kabelis tiek lietots kopā ar QDOT MICRO™ moduli, pirms šī kabeļa lietošanas ar QDOT MICRO™ moduli izlasiet CARTO™ 3 sistēmas dokumentu *Lietošanas norādījumi* un QDOT MICRO™ moduļa dokumentus *Lietošanas norādījumi un Laidiena apraksts*.
2. Šo kabeli drīkst uzstādīt un lietot tikai personāls, kurš ir izlasījis un izpratis šī dokumenta saturu.
3. Šis kabelis ir apstiprināts lietošanai tikai kopā ar Biosense Webster terapeitisko katetru. Nesavienojiet šo kabeli ne ar vienu citu katetru.
4. Šis kabelis ir paredzēts lietošanai tikai ar Biosense Webster terapeitisko kateru, savietojamu RF ģeneratoru, CARTO™ 3 sistēmu un Biosense Webster kabeļiem. Lai iegūtu sīkāku informāciju, sazinieties ar Biosense Webster pārstāvi.
5. Procedūras laikā šim kabelim jāatrodas vismaz 1 metra (39,4 collu) attālumā no CARTO™ 3 sistēmas atrašanās vietas pamatnes.
6. Lai nodrošinātu precīzus temperatūras rādījumus, pirms šī kabeļa lietošanas tas jāpievieno CARTO™ 3 sistēmas PII, tādējādi nodrošinot 5 minūšu uzsilšanas periodu. Pēc uzsilšanas perioda temperatūras rādījumi stabilizēsies. Ja kabelis tiks lietots pirms uzsilšanas perioda beigām, var rasties temperatūras novirze.

## KABEĻA UZSTĀDĪŠANA UN VADĪBA

### Kabeļa turētāja pievienošana

1. Novietojiet kabeļa turētāja (detaļas numurs M652802) skavas daļu CARTO™ sistēmas ratu roktura sānā vai uz gultas margas. Pēc tam cieši pievelciet kabeļa turētāja skrūvi.
2. Ievietojiet kabeli kabeļa turētājā, kabeli pavēršot uz leju.

### Kabeļa pievienošana

1. Pievienojiet kabeļa sarkano savienotājvadu CARTO™ 3 sistēmas PII MAP ligzdai.
2. Pievienojiet kabeļa dzelteno savienotājvadu PII QUAD B vai DECA ligzdai.

   1. piezīme. Abiem savienotājvadiem jābūt pievienotiem PII.

   2. piezīme. Savienotāja pievienošana QUAD A var radīt nevēlamu EKG troksni.
3. Ja izmantojat QDOT™ mikrokatetru, pievienojiet katetru vienam TX *eco* EXT kabeļa galam. Pievienojiet otru TX *eco* EXT kabeļa galu lielajai ligzdai TX *eco* kabeļa galā.
4. Ja izmantojat citu Biosense Webster terapeitisko katetru, pievienojiet katetru vienam pagarinājuma kabeļa galam. Pievienojiet otru pagarinājuma kabeļa galu mazajai, apaļajai ligzdai TX *eco* kabeļa galā.

### Kabeļa atvienošana

1. Atvienojiet sarkano savienotājvadu no CARTO™ 3 sistēmas PII, pavelkot savienotājvadu aiz slīdošās atvienošanas satveres daļas.
2. Tad atvienojiet dzelteno savienotājvadu no PII, pavelkot savienotājvadu aiz slīdošās satveres daļas.

   Piezīme. Abiem savienotājvadiem jābūt atvienotiem no PII. Neatstājiet vienu kabeli pievienotu un otru – atvienotu.
3. Pēc kabeļa atvienošanas jāpagaida 10 sekundes pirms kabeļa atkārtotas pievienošanas PII.

### LED indikatora stāvoklis

Par kabeļa stāvokli norāda LED indikators. Kad kabelis ir pareizi pievienots CARTO™ 3 sistēmas PSI un Biosense Webster terapeitiskajam katetram, tiek veikts iebūvētais tests (IT).

| LED indikators | Kabeļa stāvoklis | Komentāri |
|---|---|---|
| Zaļa gaisma: mirgo lēnām | Notiek IT | --- |
| Zaļa gaisma: nepārtraukta | Gatavs lietošanai | --- |
| Sarkana gaisma: mirgo ātri | Kļūda, IT neizdevās | Temperatūras rādījumi vēl nav nosūtīti CARTO™ 3 sistēmai vai RF ģeneratoram.<br>Skatiet sadaļu *Traucējummeklēšana* šajā dokumentā. |

## KABEĻA APRŪPE

### Tīrīšana

Kabelim nav nepieciešama dezinfekcija vai sterilizācija. Neizmantojiet autoklāvu, tvaika vai citas kabeļa sterilizācijas metodes.

Ja uz kabeļa parādās putekļi vai netīrumi, notīriet to šādi:

1. Atvienojiet kabeli.
2. Tīriet kabeļa ārējo apvalku ar drānu, kas samitrināta ūdenī, kam pievienotas spirtu nesaturošas roku ziepes.
3. Nodrošiniet, lai ziepju šķīdums neiekļūtu kabeļa savienotājvados vai ligzdās.
4. Pārliecinieties, vai kabelis ir sauss, pirms to pievienojat CARTO™ 3 sistēmai vai katetram.

### Apkope

Kabelim nav tādu detaļu, kuru apkopi varētu nodrošināt tā lietotājs. Ja kabeļa lietošana ir nesekmīga, sazinieties ar klientu atbalsta centru vai Biosense Webster pārstāvi, lai saņemtu jaunu kabeli. Paredzētais kabeļa lietderīgās lietošanas laiks ir trīs gadi.

### Utilizācija

Nododiet sastāvdaļas otrreizējai pārstrādei vai utilizējiet produktu un tā neizmantotos elementus vai atkritumus saskaņā ar vietējiem likumiem un noteikumiem.

## TEHNISKIE DATI

### Specifikācijas

| | |
|---|---|
| **Līdzstrāvas ieeja** | Kabelis saņem jaudu no CARTO™ 3 sistēmas PII. |
| **Svars** | 1 kg (2,2 mārc.) |
| **Izmēri** | 10 in garš x 1,9 in plats x 3 in augsts<br>(254 mm x 48 mm x 76 mm) |
| **Temperatūras precizitāte** | ≤ 2 °C |

### Ekspluatācijas, uzglabāšanas un piegādes nosacījumi

| | Minimums | Maksimums |
|---|---|---|
| **Ekspluatācijas nosacījumi** | | |
| Apkārtējās vides temperatūra | 10 °C | 30 °C |
| Relatīvais mitrums* | 25 % | 75 % |
| **Glabāšanas un piegādes apstākļi** | | |
| Apkārtējās vides temperatūra | –30 °C | 65 °C |
| Relatīvais mitrums* | 10 % | 95 % |

*Saskaņā ar Standartu MIL-STD-1695 relatīvajam mitrumam jābūt robežās no 30 % līdz 70 % vietās, kur ražo vai apstrādā elektroniskās detaļas un hibrīdās mikroshēmas. Saskaņā ar Standartu MIL-STD-1695 apstrādes un uzglabāšanas vietā jānodrošina vienāda līmeņa relatīvā mitruma kontrole, izņemot ja priekšmeti ir pārklāti vai aizsargāti.

### Informācija par EMS

TX *eco* kabelis ir paredzēts izmantošanai elektromagnētiskajā vidē, kā norādīts CARTO™ 3 sistēmas *lietošanas instrukcijā*.

## TRAUCĒJUMMEKLĒŠANA

Ja LED indikators uz TX *eco* kabeļa ir sarkans un ātri mirgo, BIT nav izdevies un ir izraisījis kļūdu (skatiet sadaļu *LED indikatora stāvoklis* šajā dokumentā). Lai novērstu problēmu, veiciet tālāk norādītās darbības.

1. Atvienojiet katetru no kabeļa.
2. Atvienojiet kabeli no CARTO™ 3 sistēmas PII.
3. Atkārtoti pievienojiet kabeli PII.
4. Atkārtoti pievienojiet katetru kabelim.
5. Ja tiek lietots QDOT MICRO™ modulis, ievērojiet norādījumus QDOT MICRO™ moduļa dokumentos *Lietošanas norādījumi un Laidiena apraksts*.
6. Ja kabeļa lietošana ir nesekmīga, sazinieties ar klientu atbalsta centru vai Biosense Webster pārstāvi.

Dažos gadījumos, kad sistēmai piemēro 15 kV gaisa izlādi vai 8 kV kontaktizlādi, CARTO™ 3 sistēmā tiek vienlaikus parādīti 3 kļūdu ziņojumi: Map points cannot be acquired (Nevar iegūt kartes punktus) (401. kļūda), Patient Body Reference has moved (Pacienta ķermeņa atsauce nobīdīta) (256. kļūda) un uznirstošais logs ar ziņojumu Patient Body Reference Atsauces change (Pacienta ķermeņa atsauce mainīta). Šajā gadījumā restartējiet PIU.

## GARANTIJAS ATRUNA UN ATBILDĪBAS IEROBEŽOJUMI

**UZ ŠEIT APRAKSTĪTO(-AJIEM) IZSTRĀDĀJUMU(-IEM) NEATTIECAS NEKĀDA TIEŠA VAI NETIEŠA GARANTIJA, TOSTARP, BET NE TIKAI NEKĀDA NETIEŠA GARANTIJA ATTIECĪBĀ UZ PĀRDOŠANAI PIEMĒROTU KVALITĀTI VAI DERĪGUMU NOTEIKTAM MĒRĶIM. NEKĀDOS APSTĀKĻOS BIOSENSE WEBSTER, INC. VAI AR TO SAISTĪTIE UZŅĒMUMI NAV ATBILDĪGI PAR JEBKĀDIEM FAKTISKAJIEM, TIEŠAJIEM, NEJAUŠAJIEM, IZRIETOŠAJIEM VAI CITĀDIEM ZAUDĒJUMIEM CITĀDI KĀ VIEN TĀ, KĀ TAS IR SKAIDRI NOTEIKTS PIEMĒROJAMAJĀ LIKUMĀ.**

**NEIEROBEŽOJOT IEPRIEKŠMINĒTO, BIOSENSE WEBSTER, INC. VAI AR TO SAISTĪTIE UZŅĒMUMI NAV ATBILDĪGI NE PAR KĀDIEM FAKTISKAJIEM, TIEŠAJIEM, NEJAUŠAJIEM, IZRIETOŠAJIEM VAI CITĀDIEM ZAUDĒJUMIEM, KAS RADUŠIES, IZMANTOJOT VIENU VAI VAIRĀKUS IZSTRĀDĀJUMUS, KURI MARĶĒTI KĀ VIENREIZĒJAI LIETOŠANAI PAREDZĒTI VAI KURU ATKĀRTOTA IZMANTOŠANA IR AIZLIEGTA AR ATTIECĪGU LIKUMU.**

Apraksti un specifikācijas, kas atrodamas Biosense Webster, Inc. drukātajā materiālā, ieskaitot šo publikāciju, ir tikai informatīvi un domāti tikai, lai vispārīgi aprakstītu produktu (-us) tā (to) ražošanas laikā un nav izdoti kā jebkāda veida konkrētā (-o) produkta (-u) garantija.

## LIETOŠANAS NORĀDĪJUMI ELEKTRONISKĀ VEIDĀ

Šis dokuments ir pieejams šeit: www.e-ifu.com.

# Кабел TX *eco*

**Внимание: Федералното право на САД ја ограничува продажбата на овој уред; имено, уредот може да биде продаден само на лиценциран здравствен работник или по нарачка на лиценциран здравствен работник.**

- Да не се користи ако амбалажата е отворена или оштетена.

## ОПИС НА УРЕДОТ

Кабелот TX *eco* се користи со продолжителен кабел за поврзување на терапевтски катетер Biosense Webster со интерфејс-единицата за пациенти (ИЕП) на системот CARTO™ 3 (верзија 6 и понови верзии). Продолжителните кабли се наведени подолу:

- За микрокатетерот QDOT™: кабел TX *eco* EXT D135703
- За други терапевтски катетери Biosense Webster: D128603 (каталог бр. CR3434CT) или D128604 (каталог бр. CR3425CT)

Кабелот TX *eco* пренесува податоци од терапевтски катетер Biosense Webster до системот CARTO™ 3 и РФ-генераторот. Информациите што се пренесуваат се наведени подолу.

- Сигнали за силата
- Сигнали за локацијата
- Сигнали за пренесени информации од трите микроелектроди во врвот на катетерот (само за катетери со микроелектроди)
- Мерења на температурата од 6 термопара во врвот на катетерот

## ИНДИКАЦИИ ЗА УПОТРЕБА

Кабелот TX *eco* се користи за поврзување на терапевтски катетер Biosense Webster со интерфејс-единицата за пациенти (ИЕП) на системот CARTO™ 3 (верзија 6 и понови верзии).

## ПРЕДУПРЕДУВАЊА

1. Пред употребата на овој кабел, прочитајте го *Упатството за употреба* на терапевтскиот катетер Biosense Webster. Ако овој кабел се користи со модулот QDOT MICRO™, осврнете се на *Упатството за употреба* за системот CARTO™ 3 и *Упатството за употреба и забелешките за ослободување* за модулот QDOT MICRO™ пред употреба на овој кабел со модулот QDOT MICRO™.
2. Овој кабел може да го постави и употребува само персонал што ја прочитал и разбрал содржината на овој документ.
3. Овој кабел е потврден за употреба само со терапевтски катетер Biosense Webster. Не поврзувајте го овој кабел со ниеден друг катетер.
4. Овој кабел е наменет за употреба само со компатибилен терапевтски катетер Biosense Webster, компатибилен РФ-генератор, систем CARTO™ 3 и кабли Biosense Webster. Консултирајте се со вашиот претставник за Biosense Webster за повеќе информации.
5. Овој кабел мора да биде најмалку 1 метар (39,4 инчи) подалеку од локациската подлога на системот CARTO™ 3 за време на постапката.
6. Овој кабел мора да биде поврзан со ИЕП на системот CARTO™ 3 во период од 5 минути за загревање пред употреба за да се осигураат точни отчитувања на температурата. По периодот на загревање, отчитувањата на температурата се стабилизираат. Ако кабелот се употреби пред крајот на периодот на загревање, може да дојде до отстапување во температурата.

## ИНСТАЛИРАЊЕ И РАБОТА СО КАБЕЛОТ

### Прикачување на држачот на кабелот

1. Ставете го делот за прицврстување на држачот на кабелот (број на дел M652802) на страната со дршката на количката на системот CARTO™ или преку шината на креветот. Потоа прицврстете ја рачката на држачот на кабелот.
2. Вметнете го кабелот во држачот на кабелот, така што кабелот ќе биде свртен надолу.

### Поврзување на кабелот

1. Приклучете го црвениот приклучок на кабелот на приклучницата MAP на ИЕП на системот CARTO™ 3.
2. Приклучете го жолтиот приклучок на кабелот на приклучницата QUAD B или DECA на ИЕП.

   Забелешка 1: Двата приклучоци мора да се поврзат со ИЕП.

   Забелешка 2: Приклучување на приклучокот на QUAD A може да резултира со несакана ЕКГ бучава.
3. Доколку се користи микрокатетер QDOT™, поврзете го катетерот на едниот крај на кабелот TX *eco* EXT. Приклучете го другиот крај на кабелот TX *eco* EXT на големата приклучница на крајот од кабелот TX *eco*.
4. Ако користите друг терапевтски катетер Biosense Webster, поврзете го катетерот на едниот крај од продолжителниот кабел. Приклучете го другиот крај на продолжителниот кабел на малата кружна приклучница на крајот од кабелот TX *eco*.

### Исклучување на кабелот

1. Исклучете го црвениот приклучок од ИЕП на системот CARTO™ 3 преку повлекување на приклучокот со помош на лизгачкото странично копче за ослободување.
2. Потоа исклучете го жолтиот приклучок од ИЕП преку повлекување на приклучокот со помош на лизгачкото странично копче за ослободување.

   Забелешка: Двата приклучоци мора да се исклучат од ИЕП. Не оставајте еден кабел приклучен, а другиот исклучен.
3. По исклучување на кабелот, почекајте 10 секунди пред повторно да го приклучите кабелот на ИЕП.

### Статусни LED-светла

Статусот на кабелот се прикажува преку LED-светла. Откако кабелот правилно ќе се поврзе со ИЕП на системот CARTO™ 3 и со терапевтскиот катетер Biosense Webster, кабелот извршува Вграден Тест (BT).

| LED-светло | Статус на кабелот | Коментари |
|---|---|---|
| Зелено: бавно трепка | BT е во тек | --- |
| Зелено: постојано свети | Подготвен за употреба | --- |
| Црвено: брзо трепка | Грешка, BT неуспешен | Температурите не се испратени до системот CARTO™ 3 или РФ - генераторот.<br>Видете во делот *Решавање проблеми* на овој документ. |

## ГРИЖА ЗА КАБЕЛОТ

### Чистење

За кабелот не е потребна дезинфекција или стерилизација. Не стерилизирајте го кабелот со пареа, во автоклав или на кој било друг начин.

Доколку на кабелот се појави прав или нечистотија, исчистете го кабелот на следниов начин:

1. Исклучете го кабелот.
2. Исчистете ја надворешноста на кабелот бришејќи со навлажнета крпа со сапун за раце којшто не содржи алкохол и вода.
3. Осигурите се дека растворот со сапун нема да навлезе во приклучоците на кабелот или приклучниците.
4. Осигурите се дека кабелот е сув пред да го поврзете со системот CARTO™ 3 или со катетер.

### Одржување

Корисникот не може да ги сервисира деловите на кабелот. Ако кабелот не функционира правилно, контактирајте со одделот за поддршка на корисници или вашиот претставник на Biosense Webster за замена. Очекуваниот рок на употреба на кабелот е три години.

### Отстранување во отпад

Рециклирајте ги составните делови или фрлете ги производот и останатите елементи или отпадоци според локалните закони и регулативи.

## ТЕХНИЧКИ ПОДАТОЦИ

### Спецификации

| | |
|---|---|
| **Напојување со наизменична струја (DC)** | Кабелот се напојува со струја од ИЕП на системот CARTO™ 3. |
| **Тежина** | 1 kg (2,2 lb) |
| **Димензии** | 10 in долг x 1,9 in широк x 3 in висок (254 mm x 48 mm x 76 mm) |
| **Точност на температурата** | ≤ 2 °C |

### Спецификации за работа, складирање и транспорт

| | Минимум | Максимум |
|---|---|---|
| **Спецификации за работа** | | |
| Температура на околината | 10 °C | 30 °C |
| Релативна влажност* | 25 % | 75 % |
| **Спецификации за складирање и транспорт** | | |
| Температура на околината | -30 °C | 65 °C |
| Релативна влажност* | 10 % | 95 % |

* Во согласност со MIL-STD-1695, релативната влажност треба да биде во опсегот од 30 % до 70 % во областите каде што се ракува со електронските делови и хибридните микрокола или се обработуваат. Според MIL-STD-1695, потребно е исто ниво на контрола на релативната влажност за областите на ракување и складирање, освен кога производите се покриени или заштитени.

### Информации за електромагнетна компатибилност (EMC)

Кабелот TX *eco* е наменет за употреба во електромагнетна околина како што е наведено во *упатството за употреба* за системот CARTO™ 3.

## РЕШАВАЊЕ ПРОБЛЕМИ

Ако LED-светлото на кабелот TX *eco* е црвено и трепка брзо, BT е неуспешен и предизвикана е грешка (видете дел *Статусни LED-светла* во овој документ). Следете ги чекорите подолу за да го решите проблемот.

1. Откачете го катетрот од кабелот.
2. Откачете го кабелот од ИЕП на системот CARTO™ 3.
3. Повторно приклучете го кабелот на ИЕП.
4. Повторно поврзете го катетерот со кабелот.
5. Ако се користи модул QDOT MICRO™, следете ги насоките во *Упатството за употреба и забелешките за ослободување* за модулот QDOT MICRO™.
6. Ако проблемот не се отстрани, контактирајте со одделот за поддршка на корисници или вашиот претставник на Biosense Webster.

Во некои ситуации, каде што на системот се применува празнење на воздух од 15 kV или контактно празнење од 8 kV, системот CARTO™ 3 истовремено прикажува 3 пораки за грешка: Не може да се добијат точките за мапа (Грешка 401), Референтниот приказ за телото на пациентот се помести (Грешка 256) и скокачка порака која ја индицира промената на референтниот приказ за телото на пациентот. Доколку ова се случи, престартувајте ја ЕИП.

## ОДРЕКУВАЊЕ ОД ОДГОВОРНОСТ ВО ОДНОС НА ГАРАНЦИЈАТА И ОГРАНИЧУВАЊЕ НА ОДГОВОРНОСТА

**НЕ ПОСТОИ ЈАСНА ИЛИ ПРЕТПОСТАВЕНА ГАРАНЦИЈА, ВКЛУЧУВАЈЌИ ЈА, БЕЗ ОГРАНИЧУВАЊЕ, СЕКОЈА ПРЕТПОСТАВЕНА ГАРАНЦИЈА ЗА ПАЗАРНА КОНКУРЕНТНОСТ ИЛИ СООДВЕТНОСТ ЗА КОНКРЕТНА НАМЕНА НА ПРОИЗВОДОТ(Е) ОПИШАН(И) ОВДЕ. ПОД НИКАКВИ ОКОЛНОСТИ BIOSENSE WEBSTER, INC. ИЛИ НЕЈЗИНИТЕ ФИЛИЈАЛИ, НЕМА ДА СНОСАТ ОДГОВОРНОСТ ЗА КАКВИ БИЛО ПОСЕБНИ, ДИРЕКТНИ, СЛУЧАЈНИ, ПОСЛЕДИЧНИ ИЛИ ДРУГИ ШТЕТИ ОСВЕН АКО НЕ Е ИЗРЕЧНО ПРЕДВИДЕНО СО СООДВЕТНИОТ ЗАКОН.**

**БЕЗ ОГРАНИЧУВАЊЕ НА ГОРЕНАВЕДЕНОТО, BIOSENSE WEBSTER, INC. ИЛИ НЕЈЗИНИТЕ ФИЛИЈАЛИ, НЕМА ДА СНОСИ ОДГОВОРНОСТ ЗА КАКВИ БИЛО ПОСЕБНИ, ДИРЕКТНИ, СЛУЧАЈНИ, ПОСЛЕДИЧНИ ИЛИ ДРУГИ ШТЕТИ, КОИ ПРОИЗЛЕГУВААТ ОД ПОВТОРНАТА УПОТРЕБА НА КОЈ(И) БИЛО ПРОИЗВОД(И) КОЈ(И) Е (СЕ) ОЗНАЧЕН(И) ЗА ЕДНОКРАТНА УПОТРЕБА ИЛИ КАДЕ ШТО ПОВТОРНАТА УПОТРЕБА Е ЗАБРАНЕТА СО ВАЖЕЧКИ ЗАКОН.**

Описите и спецификациите кои се појавуваат во печатените материјали на Biosense Webster, Inc., вклучувајќи ја и оваа публикација, се само информативни и наменети само општо да се опише производот(ите) во времето на производство и не се направени или дадени како гаранција за пропишаниот производ(и) на кој било начин.

## ЕЛЕКТРОНСКО УПАТСТВО ЗА УПОТРЕБА

Овој документ е достапен на www.e-ifu.com.

# TX *eco*-kabel

**Waarschuwing: krachtens de federale wetgeving (in de VS) mag dit hulpmiddel uitsluitend door of op voorschrift van een arts worden verkocht.**

- Niet gebruiken als de verpakking is geopend of beschadigd.

## BESCHRIJVING VAN HET INSTRUMENT

De TX *eco*-kabel wordt gebruikt met een verlengkabel om een Biosense Webster therapeutische katheter aan te sluiten op de patiëntinterface-unit (PIU) van het CARTO™ 3-systeem (versie 6 en hoger). De verlengkabels worden hieronder vermeld:

- Voor de QDOT™-microkatheter: TX *eco* EXT-kabel D135703
- Voor andere Biosense Webster therapeutische katheters: D128603 (bestelnummer CR3434CT) of D128604 (bestelnummer CR3425CT)

Met de TX *eco*-kabel kunnen gegevens van een Biosense Webster therapeutische katheter naar het CARTO™ 3-systeem en de RF-generator worden verzonden. Onderstaande gegevens worden verzonden.

- Krachtsignalen
- Locatiesignalen
- IC-signalen van de 3 micro-elektroden in de tip van de katheter (alleen bij katheters met micro-elektroden)
- Temperatuurmetingen van de 6 thermokoppels in de tip van de katheter

## INDICATIES VOOR GEBRUIK

De TX *eco*-kabel wordt gebruikt om een Biosense Webster therapeutische katheter aan te sluiten op de patiëntinterface-unit (PIU) van het CARTO™ 3-systeem (versie 6 en hoger).

## WAARSCHUWINGEN

1. Lees de *gebruiksaanwijzing* van de Biosense Webster therapeutische katheter voordat u deze kabel gebruikt. Als u deze kabel gebruikt in combinatie met de QDOT MICRO™-module, moet u de *gebruiksaanwijzing* van het CARTO™ 3-systeem en de *gebruiksaanwijzing en de release notes* van de QDOT MICRO™-module lezen voordat u deze kabel met de QDOT MICRO™-module gebruikt.
2. Alleen personeel dat de inhoud van dit document heeft gelezen en begrepen, mag deze kabel aansluiten en gebruiken.
3. Deze kabel is alleen goedgekeurd voor gebruik met een Biosense Webster therapeutische katheter. Sluit deze kabel niet aan op andere katheters.
4. Deze kabel is uitsluitend bestemd voor gebruik in combinatie met een Biosense Webster therapeutische katheter, een compatibele RF-generator, een CARTO™ 3-systeem en kabels van Biosense Webster. Neem contact op met de vertegenwoordiger van Biosense Webster voor nadere informatie.
5. Houd deze kabel tijdens de procedure op minimaal 1 meter (39,4 inch) afstand van het locatiepaneel van het CARTO™ 3-systeem.
6. Sluit deze kabel aan op de PIU van het CARTO™ 3-systeem en laat het systeem voorafgaand aan het gebruik 5 minuten opwarmen, zodat u nauwkeurige temperatuurmetingen verkrijgt. Na de opwarmperiode worden de temperatuurwaarden stabiel. De temperatuurwaarden kunnen schommelen als u de kabel gebruikt voordat de opwarmperiode voorbij is.

## DE KABEL AANSLUITEN EN GEBRUIKEN

### De kabelhouder bevestigen

1. Plaats de klem van de kabelhouder (onderdeelnummer M652802) aan de zijkant van de handgreep van de wagen van het CARTO™-systeem of aan het bedhek. Draai vervolgens de knop van de kabelhouder vast.
2. Plaats de kabel in de kabelhouder met de kabel naar beneden gericht.

### De kabel aansluiten

1. Sluit de rode kabelaansluiting aan op het MAP-aansluitpunt van de PIU van het CARTO™ 3-systeem.
2. Sluit de gele kabelaansluiting aan op het QUAD B- of DECA-aansluitpunt van de PIU.

   Opmerking 1: beide kabelaansluitingen moeten op de PIU worden aangesloten.

   Opmerking 2: er kan ongewenste ecg-ruis optreden wanneer u de kabelaansluiting op QUAD A aansluit.
3. Als u een QDOT™-microkatheter gebruikt, sluit u de katheter aan op een van de uiteinden van de TX *eco* EXT-kabel. Sluit het andere uiteinde van de TX *eco* EXT-kabel aan op de grote contrastekker van de TX *eco*-kabel.
4. Als u een andere Biosense Webster therapeutische katheter gebruikt, sluit u de katheter aan op een uiteinde van de verlengkabel. Sluit het andere uiteinde van de verlengkabel aan op het kleine ronde contrastekkertje van de TX *eco*-kabel.

### De kabel loskoppelen

1. Koppel de rode aansluiting los van de PIU van het CARTO™ 3-systeem door aan het ontkoppelingsgedeelte van de aansluiting te trekken.
2. Koppel vervolgens de gele aansluiting los van de PIU door aan het ontkoppelingsgedeelte van de aansluiting te trekken.

   Opmerking: beide kabelaansluitingen moeten worden losgekoppeld van de PIU. Laat niet de ene kabel aangesloten en de andere losgekoppeld.
3. Wacht na het loskoppelen van de kabel 10 seconden voordat u de kabel weer aansluit op de PIU.

### Ledstatuslampje

De status van de kabel wordt aangegeven door een ledlampje. De kabel voert een ingebouwde test (Built-In Test, BIT) uit, nadat de kabel goed is aangesloten op de PIU van het CARTO™ 3-systeem en de Biosense Webster therapeutische katheter.

| Ledlampje | Kabelstatus | Opmerkingen |
|---|---|---|
| Groen: knippert langzaam | Bezig met testen | --- |
| Groen: brandt continu | Klaar voor gebruik | --- |
| Rood: knippert snel | Fout, test mislukt | De temperatuurwaarden worden niet verzonden naar het CARTO™ 3-systeem of de RF -generator.<br>Lees het hoofdstuk *Probleemoplossing* in dit document. |

## DE KABEL ONDERHOUDEN

### Reinigen

De kabel hoeft niet gedesinfecteerd of gesteriliseerd te worden. Steriliseer de kabel niet met behulp van stoomsterilisatie, een autoclaaf of een andere methode.

Reinig de kabel als volgt als u stof of vuil op de kabel ziet:

1. Koppel de kabel los.
2. Veeg de buitenkant van de kabel schoon met een doekje en wat alcoholvrij zeepsop.
3. Zorg ervoor dat er geen zeepsop in de kabelaansluitingen of aansluitpunten terechtkomt.
4. Zorg ervoor dat de kabel droog is voordat u hem op het CARTO™ 3-systeem of een katheter aansluit.

### Onderhoud

De kabel bevat geen onderdelen die door de gebruiker gerepareerd kunnen worden. Als de kabel niet meer werkt, kunt u contact opnemen met de klantenservice of uw Biosense Webster-vertegenwoordiger voor een nieuwe kabel. De verwachte gebruiksduur van de kabel is drie jaar.

### Afvoer

Recycle de onderdelen of voer het product en de restanten of het afval ervan af overeenkomstig de lokale wet- en regelgeving.

## TECHNISCHE GEGEVENS

### Specificaties

| | |
|---|---|
| **Stroomvoorziening** | De kabel wordt door de PIU van het CARTO™ 3-systeem van stroom voorzien. |
| **Gewicht** | 1 kg (2,2 lb) |
| **Afmetingen** | 254 lang x 48 breed x 76 mm hoog |
| **Nauwkeurigheid van de temperatuurwaarde** | ≤ 2 °C |

### Specificaties voor bediening, opslag en transport

| | Minimum | Maximum |
|---|---|---|
| **Bedieningsspecificaties** | | |
| Omgevingstemperatuur | 10 °C | 30 °C |
| Relatieve vochtigheid* | 25% | 75% |
| **Specificaties voor opslag en transport** | | |
| Omgevingstemperatuur | -30 °C | 65 °C |
| Relatieve vochtigheid* | 10% | 95% |

* Conform MIL-STD-1695 moet de relatieve luchtvochtigheid binnen het bereik van 30-70% vallen op plaatsen waar elektronische onderdelen en hybride microcircuits worden gebruikt of verwerkt. Volgens MIL-STD-1695 geldt hetzelfde bereik voor de relatieve luchtvochtigheid voor plaatsen waar onderdelen worden gebruikt en opgeslagen, tenzij ze bedekt of beschermd zijn.

### EMC-informatie

De TX *eco*-kabel is bestemd voor gebruik in een elektromagnetische omgeving zoals aangegeven in de *gebruiksaanwijzing* van het CARTO™ 3-systeem.

## PROBLEEMOPLOSSING

Als het ledlampje van de TX *eco*-kabel rood is en snel knippert, is de ingebouwde test mislukt en is er een fout opgetreden (zie paragraaf *Ledstatuslampje* in dit document). Volg de onderstaande stappen om het probleem op te lossen.

1. Koppel de katheter los van de kabel.
2. Koppel de kabel los van de PIU van het CARTO™ 3-systeem.
3. Sluit de kabel weer aan op de PIU.
4. Sluit de katheter weer aan op de kabel.
5. Als u een QDOT MICRO™-module gebruikt, moet u de aanwijzingen in de *gebruiksaanwijzing en release notes* van de QDOT MICRO™-module volgen.
6. Neem contact op met de klantenservice of uw vertegenwoordiger van Biosense Webster als het probleem aanhoudt.

In sommige gevallen, als er 15 kV ontlading via de lucht of 8 kV ontlading via contact op het systeem wordt aangelegd, kunnen er op het CARTO™ 3-systeem drie foutmeldingen tegelijk worden weergegeven: 'Map points cannot be acquired' (kaartpunten niet gevonden; fout 401), 'Patient Body Reference has moved' (patiëntlichaam-referentie is verplaatst; fout 256) en een pop-up om aan te geven dat de referentie voor het lichaam van de patiënt is veranderd. In dat geval moet de PIU opnieuw worden gestart.

## AFSTANDSVERKLARING VAN GARANTIE EN BEPERKING VAN AANSPRAKELIJKHEID

**OP HET HIERIN BESCHREVEN PRODUCT BESTAAT GEEN EXPLICIETE OF IMPLICIETE GARANTIE, HIERONDER ZONDER BEPERKING BEGREPEN ENIGE IMPLICIETE GARANTIE VAN VERHANDELBAARHEID OF GESCHIKTHEID VOOR EEN BEPAALD DOEL. ONDER GEEN BEDING ZAL BIOSENSE WEBSTER, INC., OF DAARBIJ AANGESLOTEN BEDRIJVEN, AANSPRAKELIJK ZIJN VOOR ENIGERLEI SPECIALE, DIRECTE, INCIDENTELE, GEVOLG- OF ANDERE SCHADE, TENZIJ ZULKS UITDRUKKELIJK BIJ DE TOEPASSELIJKE WET IS VOORGESCHREVEN.**

**ONVERMINDERD HET VOORGAANDE ZAL BIOSENSE WEBSTER, INC. OF HAAR GEAFFILIEERDE BEDRIJVEN NIET AANSPRAKELIJK ZIJN VOOR ENIGE SPECIALE, DIRECTE, BIJKOMENDE OF GEVOLGSCHADE OF ANDERE SCHADE, VOORTVLOEIEND UIT HET HERGEBRUIK VAN ENIG(E) PRODUCT(EN) VOOR ENKELVOUDIG GEBRUIK OF WAAR HERGEBRUIK VERBODEN IS DOOR DE TOEPASSELIJKE WET.**

Beschrijvingen en specificaties in drukwerk van Biosense Webster, Inc., met inbegrip van deze publicatie, zijn enkel bedoeld als een algemene beschrijving van het product ten tijde van de vervaardiging ervan en vormen geen garantie voor het beschreven product.

## ELEKTRONISCHE GEBRUIKSAANWIJZING

Dit document is beschikbaar op www.e-ifu.com.

# TX *eco*-kabel

**Obs: Ifølge amerikansk føderal lovgivning kan denne enheten kun selges eller bestilles av lisensiert helsepersonell.**

- Må ikke brukes hvis pakningen er åpnet eller skadet.

## BESKRIVELSE AV ENHETEN

TX *eco*-kabelen brukes med en forlengelseskabel for å koble et Biosense Webster terapeutisk kateter til pasient-grensesnittenheten (PIU) på CARTO™ 3-systemet (versjon 6 og senere). Forlengelseskablene er oppført nedenfor:

- For QDOT™-mikrokateteret: TX *eco* EXT-kabel D135703
- For andre Biosense Webster terapeutiske katetre: D128603 (katalognr. CR3434CT) eller D128604 (katalognr. CR3425CT)

TX *eco* kabelen kommuniserer data fra et Biosense Webster terapeutisk kateter til CARTO™ 3-systemet og RF-generatoren. Den kommuniserte informasjonen er opplistet nedenfor.

- Styrkesignaler
- Lokaliseringssignaler
- IC-signalene fra de 3 mikroelektrodene i tuppen på kateteret (kun for katetre med mikroelektroder)
- Temperaturmålingene fra de 6 termoelementene i tuppen på kateteret

## INDIKASJONER FOR BRUK

TX *eco* -kabelen skal brukes til å koble et Biosense Webster terapeutisk kateter til pasientgrensesnittenheten (PIU) i CARTO™ 3-systemet (versjon 6 og senere).

## ADVARSLER

1. Før du bruker denne kabelen, må du lese *bruksanvisningen* for det terapeutiske kateteret fra Biosense Webster. Hvis kabelen brukes med QDOT MICRO™-modulen, les *bruksanvisningen* for CARTO™ 3-systemet og *bruksanvisningen og utgivelsesmerknadene* for QDOT MICRO™-modulen før du bruker denne kabelen sammen med QDOT MICRO™-modulen.
2. Kun personale som har lest og forstått innholdet i dette dokumentet, kan konfigurere og bruke denne kabelen.
3. Denne kabelen er kun godkjent for bruk med et Biosense Webster terapeutisk kateter. Ikke koble denne kabelen til et annet kateter.
4. Denne kabelen skal kun brukes med et Biosense Webster terapeutisk kateter, en kompatibel RF-generator, et CARTO™ 3-system og Biosense Webster kabler. Ta kontakt med din Biosense Webster-representant for ytterligere informasjon.
5. Denne kabelen må være minst 1 meter (39,4") vekk fra lokaliseringsputen for CARTO™ 3-systemet under prosedyren.
6. Denne kabelen må være koblet til PIU-en på CARTO™ 3-systemet i en 5 minutters oppvarmingsperiode for å sørge for at temperaturavlesningene er nøyaktige. Etter oppvarmingsperioden stabiliserer temperaturavlesningene seg. Dersom kabelen blir brukt før oppvarmingsperioden er fullført, kan det forekomme temperaturavvik.

## INSTALLASJON OG BRUK AV KABELEN

### Festing av kabelholderen

1. Plasser klemmedelen på kabelholderen (delenummer M652802) på siden av CARTO™-systemets vognhåndtak eller over sengerekkverket. Stram deretter knappen på kabelholderen.
2. Før inn kabelen i kabelholderen med kabelen pekende ned.

### Tilkobling av kabelholderen

1. Koble kabelens røde kobling til MAP-uttaket på pasientgrensesnittenheten på CARTO™ 3-systemet.
2. Koble kabelens gule kobling til QUAD B- eller DECA-uttaket på pasientgrensesnittenheten.

   Merk 1: Begge koblinger må være koblet til pasientgrensesnittenheten.

   Merk 2: Kobling av koblinger til QUAD A kan føre til uønsket EKG-støy.
3. Hvis det brukes et QDOT™-mikrokateter, koble kateteret til den ene enden av TX *eco* EXT-kabelen. Koble den andre enden av TX *eco* EXT-kabelen til den store kontakten på enden av TX *eco* -kabelen.
4. Hvis du bruker et annet Biosense Webster terapeutisk kateter, kobler du kateteret til den ene enden av forlengelseskabelen. Koble den andre enden av forlengelseskabelen til den smale, runde kontakten på enden av TX *eco*-kabelen.

### Frakobling av kabelen

1. Koble den røde koblingen fra pasientgrensesnittenheten på CARTO™ 3-systemet ved å trekke koblingen fra skyvegrepet.
2. Koble deretter den gule koblingen fra pasientgrensesnittenheten ved å trekke koblingen fra skyvegrepet.

   Merk: Begge koblinger må være koblet fra pasientgrensesnittenheten. La aldri én kabel være tilkoblet og en annen kabel være frakoblet.
3. Etter at kabelen er koblet fra, vent i 10 sekunder før du kobler kabelen til PIU-en på nytt.

### LED-status

Kabelens status er indikert av et LED-symbol. Etter at kabelen er riktig koblet til pasient-grensesnittenheten på CARTO™ 3-systemet, og til et Biosense Webster terapeutisk kateter, gjennomfører kabelen en innebygget test (BIT).

| LED | Kabelstatus | Kommentarer |
|---|---|---|
| Grønn: sakte blinking | BIT kjører | --- |
| Grønn: lyser kontinuerlig | Klar til bruk | --- |
| Rød: hurtig blinking | Feil, BIT feilet | Temperaturene blir ikke sendt til CARTO™ 3-systemet eller RF-generatoren.<br>Se avsnittet *Feilsøking* i dette dokumentet. |

## VEDLIKEHOLD AV KABELEN

### Rengjøring

Kabelen krever ikke desinfeksjon eller sterilisering. Kabelen skal ikke dampes, autoklaveres eller på andre måter steriliseres.

Dersom støv eller rusk samler seg på kabelen, rengjør kabelen slik:

1. Koble kabelen fra.
2. Rengjør kabelen ved å tørke av den med en klut fuktet med alkoholfri håndsåpe og vann.
3. Forsikre deg om at såpeløsningen ikke kommer inn i koblingene eller uttakene.
4. Forsikre deg om at kabelen er tørr før den kobles til CARTO™ 3-systemet eller et kateter.

### Vedlikehold

Det finnes ingen deler i kabelen som brukeren kan utføre service på. Dersom kabelen slutter å virke, kontakt kundeservice eller din Biosense Webster representant for utskiftning. Forventet levetid for kabelen er tre år.

### Kassering

Resirkuler komponentene, eller kast produktet og restelementene eller avfallet i henhold til lokale lover og forskrifter.

## TEKNISKE DATA

### Spesifikasjoner

| | |
|---|---|
| **Likestrøm innkobling** | Kabelen forsynes med strøm fra PUI-en på CARTO™ 3-systemet. |
| **Vekt** | 1 kg (2,2 pund) |
| **Mål** | 10 tommer lengde x 1,9 tommer bredde x 3 tommer høyde (254 mm x 48 mm x 76 mm) |
| **Temperaturnøyaktighet** | ≤ 2 °C |

### Bruks-, lagrings- og forsendelsesspesifikasjoner

| | Minimum | Maksimum |
|---|---|---|
| **Bruksspesifikasjoner** | | |
| Omgivelsestemperatur | 10 °C | 30 °C |
| Relativ fuktighet* | 25 % | 75 % |
| **Lagrings- og forsendelsesspesifikasjoner** | | |
| Omgivelsestemperatur | -30 °C | 65 °C |
| Relativ fuktighet* | 10 % | 95 % |

* I henhold til MIL-STD-1695, skal de relative fuktighetsnivåene være innenfor rekkevidden av 30 % til 70 % i områder hvor elektroniske deler og hybride mikrokretser håndteres eller brukes. MIL-STD-1695 krever samme nivå av relative fuktighetskontroller for håndtering og lagringsområder, bortsett fra når gjenstandene er tildekket og beskyttet.

### EMC-informasjon

TX *eco*-kabelen er tiltenkt brukt i et elektromagnetisk miljø slik det er spesifisert i *bruksanvisningen* for CARTO™ 3-systemet.

## FEILSØKING

Dersom LED-lyset på TX *eco*-kabelen er rødt og blinker hurtig, har BIT-testen feilet og har forårsaket en feil (se avsnittet *LED-status* i dette dokumentet). Følg trinnene under for å korrigere problemet.

1. Koble kateteret fra kabelen.
2. Koble kabelen fra pasient-grensesnittenheten på CARTO™ 3-systemet.
3. Koble kabelen til pasient-grensesnittenheten igjen.
4. Koble kateteret til kabelen igjen.
5. Dersom en QDOT MICRO™-modul blir brukt, følg anvisningene i *bruksanvisningen og distribusjonsnotatene* for QDOT MICRO™-modulen.
6. Dersom problemet vedvarer, kontakt kundeservice eller din Biosense Webster-representant.

I enkelte situasjoner, der 15 kV luftutblåsning eller 8 kV kontaktutblåsning påføres systemet, viser CARTO™ 3-systemet tre feilmeldinger samtidig: Kartpunkter kan ikke innhentes (feil 401), pasientkroppreferanse er flyttet (feil 256) og en popup-melding som indikerer pasientkroppreferanse-endringen. Hvis dette skjer, start pasientgrensesnittenheten på nytt.

## ANSVARSFRASKRIVELSE OG GARANTIBEGRENSNING

**DET FINNES INGEN SÆRSKILT ELLER INDIREKTE GARANTI, INNBEFATTET, UTEN BEGRENSNING, IMPLISITTE GARANTIER FOR SALGBARHET ELLER EGNETHET FOR ET BESTEMT FORMÅL FOR PRODUKTET/ENE SOM ER BESKREVET HER. IKKE UNDER NOEN OMSTENDIGHET VIL BIOSENSE WEBSTER, INC., ELLER DETS TILKNYTTEDE SELSKAPER VÆRE ANSVARLIGE FOR NOEN SOM HELST SPESIELL, DIREKTE, TILFELDIG, PÅFØLGENDE ELLER ANNEN SKADE, ANNET ENN DET SOM MÅTTE VÆRE UTTRYKKELIG FASTSATT I GJELDENDE LOVGIVNING.**

**UTEN BEGRENSNING AV DET FOREGÅENDE. BIOSENSE WEBSTER, INC. ELLER DETS TILKNYTTEDE SELSKAPER SKAL IKKE HA ERSTATNINGSANSVAR FOR NOEN SOM HELST SPESIELL, DIREKTE, TILFELDIG, PÅFØLGENDE ELLER ANNEN SKADE SOM KAN FØRES TILBAKE TIL GJENBRUK AV NOE(N) PRODUKT(ER) SOM ER MERKET FOR ENGANGSBRUK ELLER HVOR GJENBRUK ER FORBUDT I HENHOLD TIL GJELDENDE LOV.**

Beskrivelser og spesifikasjoner som forekommer i trykksaker fra Biosense Webster, Inc., inkludert denne publikasjonen, er kun for informasjon og er bare ment å beskrive produktet på produksjonstidspunktet og er ikke på noen måte en garanti av det beskrevede produktet.

## ELEKTRONISK BRUKSANVISNING

Dette dokumentet er tilgjengelig på www.e-ifu.com.

# Przewód TX *eco*

**Przestroga: Prawo federalne (USA) zezwala na sprzedaż tego urządzenia wyłącznie uprawnionym lekarzom lub na ich zlecenie.**

- Nie używać, jeśli opakowanie jest otwarte lub uszkodzone.

## OPIS URZĄDZENIA

Przewód TX *eco* z przedłużaczem przewodu jest stosowany do podłączenia cewnika terapeutycznego firmy Biosense Webster do jednostki interfejsu pacjenta (PIU) w systemie CARTO™ 3 (wersja 6 i nowsze). Poniżej wymieniono kable przedłużacza:

- W przypadku mikrocewnika QDOT™: przewód TX *eco* EXT D135703
- W przypadku innych cewników terapeutycznych firmy Biosense Webster: D128603 (nr katalogowy CR3434CT) lub D128604 (nr katalogowy CR3425CT)

Przewód TX *eco* przesyła dane z cewnika terapeutycznego firmy Biosense Webster do systemu CARTO™ 3 i generatora RF. Typy przekazywanych informacji wymieniono poniżej:

- Sygnały siły
- Sygnały lokalizacji
- Sygnały IC z 3 mikroelektrod znajdujących si w końcówce cewnika (wyłącznie w przypadku cewników z mikroelektrodami)
- Pomiary temperatury z 6 termopar znajdujących si w końcówce cewnika

## WSKAZANIA DO STOSOWANIA

Przewód TX *eco* jest stosowany do podłączenia cewnika terapeutycznego firmy Biosense Webster do jednostki interfejsu pacjenta (PIU) w systemie CARTO™ 3 (wersja 6 i nowsze).

## OSTRZEŻENIA

1. Przed użyciem przewodu należy przeczytać *instrukcj obsługi* cewnika terapeutycznego firmy Biosense Webster. Jeśli przewód jest stosowany z modułem QDOT MICRO™, należy zapoznać si z *instrukcją obsługi* systemu CARTO™ 3 oraz *instrukcją obsługi i informacjami dotyczącymi wersji* modułu QDOT MICRO™ przed rozpocz ciem korzystania z przewodu z modułem QDOT MICRO™.
2. Przewód może być konfigurowany i użytkowany wyłącznie przez osoby, które przeczytały niniejszy dokument i rozumieją jego treść.
3. Przewód został zatwierdzony do użytku wyłącznie z cewnikiem terapeutycznym firmy Biosense Webster. Nie wolno podłączać go do żadnych innych cewników.
4. Przewód przeznaczony jest do użycia z terapeutycznym cewnikiem firmy Biosense Webster, kompatybilnym generatorem RF, systemem CARTO™ 3 oraz przewodami firmy Biosense Webster. Szczegółowe informacje można uzyskać u przedstawiciela firmy Biosense Webster.
5. W trakcie zabiegu przewód musi znajdować si w odległości co najmniej 1 metra (39,4 cala) od podkładki lokalizacyjnej systemu CARTO™ 3.
6. W celu zapewnienia dokładnych odczytów temperatury przewód musi przed użyciem zostać podłączony do PIU systemu CARTO™ 3 na 5-minutowy okres rozgrzewania. Po okresie rozgrzewania odczyty temperatury stabilizują si . Jeśli przewód b dzie używany przed zakończeniem okresu rozgrzewania, wskazania temperatury mogą być niepoprawne.

## INSTALACJA I OBSŁUGA PRZEWODU

### Podłączanie uchwytu przewodu

1. Zacisk uchwytu przewodu (nr kat. M652802) umieścić z boku uchwytu wózka systemu CARTO™ lub na por czy łóżka. Dokr cić pokr tło na uchwycie przewodu.
2. Wprowadzić przewód do uchwytu przewodu, kierując przewód do dołu.

### Podłączanie przewodu

1. Czerwone złącze przewodu podłączyć do gniazda MAP na PIU systemu CARTO™ 3.
2. Żółte złącze przewodu podłączyć do gniazda QUAD B lub DECA na PIU.

   Uwaga 1: oba złącza muszą być podłączone do PIU.

   Uwaga 2: podłączenie złącza do QUAD A może doprowadzić do wystąpienia niepożądanego szumu EKG.
3. W przypadku korzystania z mikrocewnika QDOT™ należy podłączyć cewnik do jednego końca przewodu TX *eco* EXT. Drugi koniec przewodu TX *eco* EXT podłączyć do dużego gniazda na końcu przewodu TX *eco*.
4. W przypadku stosowania kolejnego cewnika terapeutycznego Biosense Webster należy podłączyć cewnik do jednego końca przedłużacza przewodu. Drugi koniec przedłużacza przewodu podłączyć do małego, okrągłego gniazda na końcu przewodu TX *eco*.

### Odłączanie przewodu

1. Odłączyć czerwone złącze od PIU systemu CARTO™ 3, wyciągając je z przesuwanego uchwytu zwalniającego.
2. Nast pnie odłączyć żółte złącze od PIU, wyciągając je z przesuwanego uchwytu zwalniającego.

   Uwaga: oba złącza muszą być odłączone od PIU. Nie pozostawiać jednego przewodu podłączonego, a drugiego odłączonego.
3. Po odłączeniu przewodu należy poczekać 10 sekund przed ponownym podłączeniem przewodu do PIU.

### Kontrolka LED statusu

Status przewodu wskazuje kontrolka LED. Po poprawnym podłączeniu przewodu do PIU systemu CARTO™ 3 oraz cewnika terapeutycznego firmy Biosense Webster przewód wykonuje autotest (BIT).

| Kontrolka LED | Status przewodu | Komentarze |
|---|---|---|
| Zielony: wolno miga | BIT w toku | --- |
| Zielony: świeci stałym światłem | Gotowy do użycia | --- |
| Czerwony: szybko miga | Błąd, usterka BIT | Wartości temperatury nie są przesyłane do systemu CARTO™ 3 lub generatora RF.<br>Patrz sekcja *Rozwiązywanie problemów* w niniejszym dokumencie. |

## PIEL GNACJA PRZEWODU

### Czyszczenie

Przewód nie wymaga dezynfekcji ani sterylizacji. Przewodu nie wolno sterylizować parą wodną, autoklawem ani poddawać sterylizacji w żaden inny sposób.

W razie pojawienia si kurzu lub zabrudzeń na przewodzie należy wyczyścić go w nast pujący sposób:

1. Odłączyć przewód.
2. Oczyścić przewód z zewnątrz, przecierając go ściereczką zwilżoną mydłem do rąk niezawierającym alkoholu i wodą.
3. Nie dopuścić do przedostania si roztworu mydła do złączy przewodu lub gniazd.
4. Przed podłączeniem przewodu do systemu CARTO™ 3 lub cewnika należy si upewnić, że jest on suchy.

### Konserwacja

Przewód nie zawiera elementów, które mogłyby być serwisowane przez użytkownika. W razie wystąpienia usterki przewodu należy skontaktować si z działem obsługi klienta lub przedstawicielem firmy Biosense Webster w celu wymiany. Przewidywany okres eksploatacji przewodu wynosi trzy lata.

### Utylizacja

Elementy wyrobu, jego pozostałości lub odpady należy poddawać recyklingowi lub wyrzucać zgodnie z lokalnymi przepisami.

## DANE TECHNICZNE

### Specyfikacje

| | |
|---|---|
| **Wejście DC** | Przewód jest zasilany z PIU systemu CARTO™ 3. |
| **Masa** | 1 kg (2,2 funta) |
| **Wymiary** | 10 cali × 1,9 cala × 3 cale<br>(dł. 254 mm × szer. 48 mm × wys. 76 mm) |
| **Dokładność temperatury** | ≤ 2°C |

### Warunki pracy, przechowywania i transportu

| | Wartość minimalna | Wartość maksymalna |
|---|---|---|
| **Warunki pracy** | | |
| Temperatura otoczenia | 10°C | 30°C |
| Wilgotność wzgl dna* | 25% | 75% |
| **Warunki przechowywania i transportu** | | |
| Temperatura otoczenia | -30°C | 65°C |
| Wilgotność wzgl dna* | 10% | 95% |

* Zgodnie z MIL-STD-1695 poziomy wilgotności wzgl dnej powinny mieścić si w granicach od 30% do 70% w obszarach, w których obsługiwane lub przetwarzane są cz ś ci elektroniczne lub mikroobwody hybrydowe. MIL-STD-1695 wymaga zachowania takiego samego poziomu wilgotności wzgl dnej w obszarach przeznaczonych do pracy i przechowywania, z wyjątkiem sytuacji, kiedy elementy są osłoni te lub zabezpieczone.

### Informacje EMC

Przewód TX *eco* jest przeznaczony do stosowania w środowisku elektromagnetycznym określonym w *instrukcji obsługi* systemu CARTO™ 3.

## ROZWIĄZYWANIE PROBLEMÓW

Jeśli kontrolka LED na przewodzie TX *eco* świeci na czerwono i szybko miga, BIT zakończył si niepowodzeniem i spowodował błąd (patrz sekcja *Status LED* w niniejszym dokumencie). W celu skorygowania problemu należy wykonać poniższe czynności.

1. Odłączyć cewnik od przewodu.
2. Odłączyć przewód od PIU systemu CARTO™ 3.
3. Ponownie podłączyć przewód do PIU.
4. Ponownie podłączyć cewnik do przewodu.
5. Jeśli stosowany jest moduł QDOT MICRO™, należy post pować zgodnie ze wskazówkami podanymi w *instrukcji obsługi i uwagach dotyczących wersji* modułu QDOT MICRO™.
6. Jeżeli problem nadal wyst puje, należy skontaktować si działem obsługi klienta lub przedstawicielem firmy Biosense Webster.

W niektórych sytuacjach, gdy na system oddziałuje wyładowanie powietrzne o napi ciu 15 kV lub wyładowanie kontaktowe o napi ciu 8 kV, system CARTO™ 3 wyświetla równocześnie 3 komunikaty błędu: brak możliwości zgromadzenia punktów mapy (błąd 401), przesuni cie układu odniesienia ciała pacjenta (błąd 256) oraz komunikat o zmianie układu odniesienia ciała pacjenta. W takim przypadku należy ponownie uruchomić jednostk PIU.

## WYŁĄCZENIE I OGRANICZENIE ODPOWIEDZIALNOŚCI Z TYTUŁU GWARANCJI

**NA OPISYWANY(-E) W NINIEJSZYM DOKUMENCIE PRODUKT(Y) NIE UDZIELA SI GWARANCJI JAWNYCH ANI DOMNIEMANYCH, A W SZCZEGÓLNOŚCI, BEZ ŻADNYCH WYJĄTKÓW, DOMNIEMANEJ GWARANCJI WARTOŚCI HANDLOWEJ LUB PRZYDATNOŚCI DO OKREŚLONEGO CELU. W ŻADNYM WYPADKU BIOSENSE WEBSTER, INC. ANI FIRMY STOWARZYSZONE NIE PONOSZĄ ODPOWIEDZIALNOŚCI ZA JAKIEKOLWIEK SZCZEGÓLNE, BEZPOŚREDNIE, PRZYPADKOWE, WYNIKOWE LUB INNE SZKODY NIŻ WYRAŹNIE OKREŚLONE MAJĄCYMI ZASTOSOWANIE PRZEPISAMI PRAWNYMI.**

**NIEZALEŻNIE OD POWYŻSZEGO ZASTRZEŻENIA, FIRMA BIOSENSE WEBSTER, INC. ANI JEJ FIRMY ZALEŻNE NIE B DĄ PONOSIĆ ODPOWIEDZIALNOŚCI ZA ŻADNE SZKODY SZCZEGÓLNE, BEZPOŚREDNIE, PRZYPADKOWE, WYNIKOWE LUB INNE, WYNIKŁE W ZWIĄZKU Z PONOWNYM UŻYCIEM PRODUKTÓW OZNAKOWANYCH JAKO PRZEZNACZONE DO UŻYTKU JEDNORAZOWEGO LUB TAKICH, KTÓRYCH POWTÓRNE UŻYCIE JEST ZAKAZANE Z MOCY PRAWA.**

Opisy i dane techniczne wyst pujące w dokumentacji firmy Biosense Webster, Inc., a w szczególności w niniejszej publikacji, mają wyłącznie charakter informacyjny, stanowią ogólny opis produktu aktualny na dzień jego wytworzenia i nie zostały opracowane ani wydane jako gwarancja opisywanego produktu.

## ELEKTRONICZNA INSTRUKCJA UŻYTKOWANIA

Niniejszy dokument jest dost pny na stronie www.e-ifu.com.

# Cabo TX *eco*

**Atenção: a lei federal dos EUA limita a venda deste dispositivo a médicos ou mediante prescrição destes.**

- Não utilize se a embalagem estiver aberta ou danificada.

## DESCRIÇÃO DO DISPOSITIVO

O Cabo TX *eco* é utilizado com um cabo de extensão para ligar um cateter terapêutico da Biosense Webster à Unidade de Interface do Paciente (PIU) do Sistema CARTO™ 3 (versão 6 e seguintes). Os cabos de extensão são indicados abaixo:

- Para o Microcateter QDOT™: Cabo de extensão TX *eco* D135703
- Para outros cateteres terapêuticos da Biosense Webster: D128603 (n.º de catálogo CR3434CT) ou D128604 (n.º de catálogo CR3425CT)

O Cabo TX *eco* comunica os dados de um cateter terapêutico da Biosense Webster ao Sistema CARTO™ 3 e ao gerador de RF. As informações comunicadas são descritas abaixo.

- Sinais de força
- Sinais de localização
- Sinais IC dos 3 microelétrodos na ponta do cateter (apenas para cateteres com microelétrodos)
- Medições de temperatura dos 6 termopares na ponta do cateter

## INDICAÇÕES DE UTILIZAÇÃO

O Cabo TX *eco* é utilizado para ligar um cateter terapêutico da Biosense Webster à Unidade de Interface do Paciente (PIU) do Sistema CARTO™ 3 (versão 6 e seguintes).

## AVISOS

1. Antes de utilizar este cabo, leia as *Instruções de Utilização* do cateter terapêutico da Biosense Webster. Se este cabo estiver a ser utilizado com o Módulo QDOT MICRO™, consulte as *Instruções de Utilização* do Sistema CARTO™ 3 e as *Instruções de Utilização e Notas de Versão* do Módulo QDOT MICRO™ antes de utilizar este cabo com o Módulo QDOT MICRO™.
2. Apenas as pessoas que leram e compreenderam o conteúdo deste documento podem configurar e utilizar este cabo.
3. Este cabo só está validado para utilização com um cateter terapêutico da Biosense Webster. Não ligue este cabo a nenhum outro cateter.
4. Este cabo destina-se a ser utilizado apenas com um cateter terapêutico da Biosense Webster, um gerador de RF compatível, o Sistema CARTO™ 3 e cabos da Biosense Webster. Para mais informações, consulte o seu representante da Biosense Webster.
5. Este cabo deve estar pelo menos a 1 metro (39,4 pol.) de distância do dispositivo de localização do Sistema CARTO™ 3 durante o procedimento.
6. Este cabo deve ser ligado à PIU do Sistema CARTO™ 3 durante um período de aquecimento de 5 minutos, antes da utilização, para garantir leituras de temperatura exatas. Após o período de aquecimento, as leituras de temperatura estabilizam. Se o cabo for utilizado antes do final do período de aquecimento, poderá ocorrer um desvio de temperatura.

## INSTALAR E UTILIZAR O CABO

### Ligar o suporte do cabo

1. Coloque a parte de fixação do suporte do cabo (número de peça M652802) no lado da pega do Carro do Sistema CARTO™ ou sobre a grade da cama. De seguida, aperte o botão no suporte do cabo.
2. Insira o cabo no suporte do cabo, com o cabo virado para baixo.

### Ligar o cabo

1. Ligue o conector vermelho do cabo à tomada MAP da PIU do Sistema CARTO™ 3.
2. Ligue o conector amarelo do cabo à tomada QUAD B ou DECA na PIU.

   Nota 1: ambos os conectores devem ser ligados à PIU.

   Nota 2: ligar o conector à tomada QUAD A pode resultar num ruído indesejável de ECG.
3. Se estiver a utilizar um Microcateter QDOT™, ligue o cateter a uma extremidade do Cabo de extensão TX *eco*. Ligue a outra extremidade do Cabo de extensão TX *eco* à tomada grande na extremidade do Cabo TX *eco*.
4. Se estiver a utilizar outro cateter terapêutico da Biosense Webster, ligue-o a uma extremidade do cabo de extensão. Ligue a outra extremidade do cabo de extensão à tomada redonda pequena na extremidade do Cabo TX *eco*.

### Desligar o cabo

1. Desligue o conector vermelho da PIU do Sistema CARTO™ 3, puxando o conector da pega de libertação deslizante.
2. Em seguida, desligue o conector amarelo da PIU, puxando o conector da pega de libertação deslizante.

   Nota: ambos os conectores devem ser desligados da PIU. Não deixe um cabo ligado e o outro desligado.
3. Depois de desligar o cabo, aguarde 10 segundos antes de voltar a ligar o cabo à PIU.

### Estado do LED

O estado do cabo é indicado por um LED. Depois de o cabo estar devidamente ligado à PIU do Sistema CARTO™ 3 e ao cateter terapêutico Biosense Webster, o cabo executa um teste integrado "Built-In Test" (BIT).

| LED | Estado do cabo | Comentários |
|---|---|---|
| Verde: pisca lentamente | BIT em curso | --- |
| Verde: permanente | Pronto para utilizar | --- |
| Vermelho: pisca rapidamente | Erro, o BIT falhou | As temperaturas não são enviadas para o Sistema CARTO™ 3 nem para o gerador de RF.<br>Consulte a secção *Resolução de problemas* neste documento. |

## CUIDADOS COM O CABO

### Limpeza

O cabo não requer desinfeção ou esterilização. O cabo não deve ser esterilizado a vapor, por autoclave ou de qualquer outra forma.

Se o cabo apresentar poeiras ou detritos, limpe o cabo da seguinte forma:

1. Desligue o cabo.
2. Limpe a parte exterior do cabo utilizando um pano humedecido em água e sabonete líquido sem álcool.
3. Certifique-se de que a solução de limpeza não penetra nos conectores do cabo nem nas tomadas.
4. Certifique-se que o cabo está seco antes de o ligar ao Sistema CARTO™ 3 ou a um cateter.

### Manutenção

O cabo não contém peças que possam ser reparadas pelo utilizador. Se o cabo não funcionar, contacte o Apoio a Clientes ou o seu representante da Biosense Webster para proceder à substituição. O cabo tem uma vida útil esperada de três anos.

### Eliminação

Recicle os componentes ou elimine o produto e respetivos elementos ou artigos residuais de acordo com as leis e regulamentos locais.

## DADOS TÉCNICOS

### Especificações

| | |
|---|---|
| **Entrada CC** | O cabo recebe energia através da PIU do Sistema CARTO™ 3. |
| **Peso** | 1 kg (2,2 lb) |
| **Dimensões** | 10 pol. compr. x 1,9 pol. largura x 3 pol. altura<br>(254 mm x 48 mm x 76 mm) |
| **Precisão de temperatura** | ≤ 2 °C |

### Especificações de funcionamento, armazenamento e expedição

| | Mínimo | Máximo |
|---|---|---|
| **Especificações de funcionamento** | | |
| Temperatura ambiente | 10 °C | 30 °C |
| Humidade relativa* | 25% | 75% |
| **Especificações de armazenamento e expedição** | | |
| Temperatura ambiente | -30 °C | 65 °C |
| Humidade relativa* | 10% | 95% |

* De acordo com a norma MIL-STD-1695, os níveis de humidade relativa devem estar entre 30% e 70% em áreas de manuseamento ou processamento de peças eletrónicas e microcircuitos híbridos. A norma MIL-STD-1695 exige o mesmo nível de controlo de humidade relativa para áreas de manuseamento e armazenamento, exceto quanto os artigos estão cobertos ou protegidos.

### Informações sobre CEM

O Cabo TX *eco* destina-se a ser utilizado no ambiente eletromagnético especificado nas *Instruções de Utilização* do Sistema CARTO™ 3.

## RESOLUÇÃO DE PROBLEMAS

Se o LED no Cabo TX *eco* estiver vermelho e a piscar rapidamente, o BIT falhou e provocou um erro (consulte a secção *Estado do LED* neste documento). Siga os passos abaixo para corrigir o problema.

1. Desligue o cateter do cabo.
2. Desligue o cabo da PIU do Sistema CARTO™ 3.
3. Volte a ligar o cabo à PIU.
4. Volte a ligar o cateter ao cabo.
5. Se estiver a ser utilizado um Módulo QDOT MICRO™, siga as indicações das *Instruções de Utilização e as Notas de Versão* do Módulo QDOT MICRO™.
6. Se o problema persistir, contacte o Apoio a Clientes ou o seu representante da Biosense Webster.

Em algumas situações, em que 15 kV de descarga de ar ou 8 kV de descarga por contacto são aplicados no sistema, o Sistema CARTO™ 3 exibe 3 mensagens de erro em simultâneo: os pontos do mapa não podem ser adquiridos (Erro 401), a Referência do corpo do paciente moveu-se (Erro 256) e uma caixa de contexto a indicar a alteração da Referência do corpo do paciente. Se isto ocorrer, reinicie a PIU.

## DECLARAÇÃO DE RENÚNCIA DE GARANTIA E LIMITAÇÃO DA RESPONSABILIDADE

**NÃO HÁ NENHUMA GARANTIA EXPRESSA OU IMPLÍCITA, INCLUSIVE, MAS SEM LIMITAÇÃO, NENHUMA GARANTIA IMPLÍCITA DE ADEQUAÇÃO PARA O COMÉRCIO OU ADEQUAÇÃO PARA UM PROPÓSITO ESPECÍFICO SOBRE OS PRODUTOS DESCRITOS NO PRESENTE DOCUMENTO. A BIOSENSE WEBSTER, INC., OU AS SUAS EMPRESAS AFILIADAS, NÃO SERÃO, EM CIRCUNSTÂNCIA ALGUMA, RESPONSÁVEIS POR QUAISQUER DANOS ESPECIAIS, DIRETOS, ACIDENTAIS, CONSEQUENCIAIS OU OUTROS, PARA ALÉM DOS EXPRESSAMENTE PREVISTOS NA LEGISLAÇÃO APLICÁVEL.**

**SEM LIMITAÇÃO DO PRESENTE DISPOSITIVO, A BIOSENSE WEBSTER, INC. OU AS SUAS EMPRESAS AFILIADAS, NÃO SERÁ RESPONSÁVEL POR NENHUM DANO ESPECÍFICO, DIRETO, ACESSÓRIO OU EMERGENTE OU POR QUALQUER OUTRO DANO RESULTANTE DA REUTILIZAÇÃO DE QUAISQUER PRODUTOS QUE PORTEM ETIQUETAS PARA USO ÚNICO OU ONDE A REUTILIZAÇÃO SEJA PROIBIDA POR LEGISLAÇÃO APLICÁVEL.**

As descrições e as especificações que aparecem no material impresso da Biosense Webster, Inc., inclusive esta publicação, são apenas para fins informativos e têm a intenção exclusiva de descrever, de forma geral, o produto no momento do fabrico e não foram feitas ou dadas como garantia do produto prescrito de nenhuma forma.

## INSTRUÇÕES DE UTILIZAÇÃO ELETRÓNICAS

Este documento está disponível em www.e-ifu.com.

# Cablu TX *eco*

**Aten ie: Conform legisla iei federale (din S.U.A.), acest dispozitiv poate fi vândut numai de către un medic sau pe bază de prescrip ie medicală.**

- A nu se utiliza dacă ambalajul este deschis sau deteriorat.

## DESCRIEREA DISPOZITIVULUI

Cablul TX *eco* este utilizat cu un cablu prelungitor pentru a conecta un cateter terapeutic Biosense Webster la unitatea de interfa ă cu pacientul (PIU) a sistemului CARTO™ 3 (versiunea 6 și versiunile ulterioare). Cablurile prelungitoare sunt enumerate mai jos:

- Pentru cateterul QDOT™ Micro: cablu prelungitor TX *eco* terapeutic D135703
- Pentru alte catetere terapeutice Biosense Webster: D128603 (nr. catalog CR3434CT) sau D128604 (nr. catalog CR3425CT)

Cablul TX *eco* transmite date de la un cateter terapeutic Biosense Webster către sistemul CARTO™ 3 și generatorul RF. Informa iile transmise sunt enumerate mai jos.

- Semnale de for ă
- Semnale de pozi ie
- Semnale IC de la cei 3 microelectrozi din vârful cateterului (doar pentru catetere cu microelectrozi)
- Măsurători de temperatură de la cele 6 termocupluri de la vârful cateterului

## INDICA II DE UTILIZARE

Cablul TX *eco* este utilizat pentru a conecta un cateter terapeutic Biosense Webster la unitatea de interfa ă cu pacientul (PIU) a sistemului CARTO™ 3 (versiunea 6 și versiunile ulterioare).

## AVERTISMENTE

1. Înainte de a utiliza acest cablu, citi i *Instrucțiunile de utilizare* ale cateterului terapeutic Biosense Webster. Dacă acest cablu se utilizează împreună cu modulul QDOT MICRO™, consulta i *Instrucțiunile de utilizare* ale sistemului CARTO™ 3 și *Instrucțiunile de utilizare și notele de lansare* ale modulului QDOT MICRO™ înainte de a utiliza acest cablu împreună cu modulul QDOT MICRO™.
2. Acest cablu poate fi configurat și utilizat doar de către personal care a citit și în eles con inutul acestui document.
3. Acest cablu este validat exclusiv pentru utilizarea împreună cu un cateter terapeutic Biosense Webster. Nu conecta i acest cablu la niciun alt cateter.
4. Acest cablu este destinat utilizării doar cu un cateter terapeutic Biosense Webster, cu un generator RF compatibil, cu un sistem CARTO™ 3 și cabluri Biosense Webster. Pentru detalii consulta i reprezentantul Biosense Webster.
5. Pe parcursul procedurii, acest cablu trebuie să se afle la cel pu in 1 metru (39,4 in) de locul plăcii de localizare a sistemului CARTO™ 3.
6. Acest cablu trebuie conectat la unitatea PIU a sistemului CARTO™ 3 pentru un interval de încălzire de 5 minute înainte de utilizare pentru a asigura indica ii de temperatură exacte. După intervalul de încălzire, indica iile de temperatură se stabilizează. Dacă se utilizează cablul înainte de sfârșitul intervalului de încălzire, se poate produce o abatere de temperatură.

## INSTALAREA ȘI OPERAREA CABLULUI

### Ataşarea suportului pentru cablu

1. Plasa i por iunea cu clemă a suportului pentru cablu (cod de piesă M652802) pe partea laterală a mânerului cărucior ului sistemului CARTO™ sau peste șina patului. Apoi strânge i șurubul de fixare al suportului pentru cablu.
2. Introduce i cablul în suportul pentru cablu, cu cablul orientat în jos.

### Conectarea cablului

1. Conecta i conectorul roșu al cablului la mufa MAP de pe interfa a PIU a sistemului CARTO™ 3.
2. Conecta i conectorul galben al cablului la mufa QUAD B sau DECA de pe interfa a PIU.

   Nota 1: Ambii conectori trebuie conecta i la PIU.

   Nota 2: Conectarea conectorului la QUAD A poate conduce la interferen e EKG nedorite.
3. Dacă utiliza i un cateter QDOT™ Micro, conecta i cateterul la un capăt al cablului prelungitor TX *eco*. Conecta i celălalt capăt al cablului prelungitor *eco* terapeutic la mufa mare de la capătul cablului TX *eco*.
4. Dacă se utilizează un alt cateter terapeutic Biosense Webster, conecta i cateterul la un capăt al cablului prelungitor. Conecta i celălalt capăt al cablului prelungitor la mufa mică rotundă de la capătul cablului TX *eco*.

### Deconectarea cablului

1. Deconecta i conectorul roșu de la interfa a PIU a sistemului CARTO™ 3 trăgând conectorul de manșonul de prindere culisant.
2. Apoi deconecta i conectorul galben de la interfa a PIU trăgând conectorul de manșonul de prindere culisant.

   Notă: Ambii conectori trebuie deconecta i de la PIU. Nu lăsa i un cablu conectat și pe celălalt deconectat.
3. După deconectarea cablului, aștepta i 10 secunde înainte de a reconecta cablul la PIU.

### Indicator de stare LED

Starea cablului este indicată de un LED. După ce cablul este conectat corespunzător la interfa a PIU a sistemului CARTO™ 3 și la cateterul terapeutic Biosense Webster, cablul efectuează un test implicit (BIT).

| LED | Stare cablu | Comentarii |
|---|---|---|
| Verde: luminează intermitent lent | BIT în curs | --- |
| Verde: luminează continuu | Gata de utilizare | --- |
| Roșu: luminează intermitent rapid | Eroare, BIT nereușit | Valorile temperaturii nu sunt transmise către sistemul CARTO™ 3 sau către generatorul RF.<br>A se vedea sec iunea *Depanare* din acest document. |

## ÎNGRIJIREA CABLULUI

### Curățarea

Cablul nu necesită dezinfec ie sau sterilizare. Nu steriliza i cablul cu aburi, în autoclavă sau în alt mod.

Dacă pe cablu apar praf sau reziduuri, curăța i cablul astfel:

1. Deconecta i cablul.
2. Curăța i exteriorul cablului ștergându-l cu o lavetă umezită cu un săpun de mâini fără alcool și apă.
3. Asigura i-vă că solu ia de săpun nu pătrunde deloc în conectoarele sau mufele cablului.
4. Asigura i-vă că înainte de conectarea la sistemul CARTO™ 3 sau la un cateter cablul este curat.

### Între inere

Cablul nu con ine piese ce pot fi reparate de către utilizator. În cazul în care cablul nu func ionează, contacta i serviciul de Asisten ă Clien i sau reprezentantul dumneavoastră Biosense Webster pentru a solicita înlocuirea cablului. Durata preconizată de func ionare utilă preconizată a cablului este de trei ani.

### Eliminare

Recicla i componentele sau elimina i produsul și elementele sale reziduale sau deșeurile în conformitate cu legile și reglementările locale.

## DATE TEHNICE

### Specifica ii

| | |
|---|---|
| **Intrare CC** | Cablul este alimentat cu energie electrică de la interfa a PIU a sistemului CARTO™ 3. |
| **Greutate** | 1 kg (2,2 lb) |
| **Dimensiuni** | 10 in lungime x 1,9 in lățime x 3 in înăl ime<br>(254 mm x 48 mm x 76 mm) |
| **Acurate ea temperaturii** | ≤ 2 °C |

### Specifica ii de operare, depozitare și expediere

| | Minimum | Maximum |
|---|---|---|
| **Specifica ii de operare** | | |
| Temperatură ambiantă | 10°C | 30°C |
| Umiditate relativă* | 25% | 75% |
| **Specifica ii de depozitare și expediere** | | |
| Temperatură ambiantă | -30°C | 65°C |
| Umiditate relativă* | 10% | 95% |

*În conformitate cu MIL-STD-1695, nivelurile de umiditate relativă trebuie să se încadreze între 30% și 70% în zonele în care sunt manevrate sau procesate componentele electronice și microcircuitele hibride. MIL-STD-1695 necesită același nivel de măsuri de control pentru umiditate relativă pentru zonele de manevrare sau depozitare, cu excep ia cazului în care elementele sunt acoperite sau protejate.

### Informa ii CEM

Cablul TX *eco* este destinat utilizării în mediu electromagnetic conform specifica iilor din *Instrucțiunile de utilizare* ale sistemului CARTO™ 3.

## DEPANARE

Dacă LED-ul cablului TX *eco* este roșu și luminează intermitent rapid, BIT a eșuat și a provocat o eroare (consulta i sec iunea *Indicator de stare LED*). Urma i pașii de mai jos pentru a corecta problema.

1. Deconecta i cateterul de la cablu.
2. Deconecta i cablul de la interfa a PIU a sistemului CARTO™ 3.
3. Reconecta i cablul la PIU.
4. Reconecta i cateterul la cablu.
5. În cazul în care se utilizează un modul QDOT MICRO™, urma i indica iile din *Instrucțiunile de utilizare și Notele de lansare* ale modulului QDOT MICRO™.
6. Dacă problema persistă, contacta i serviciul de Asisten ă Clien i sau reprezentantul Biosense Webster.

În unele situa ii, în care sistemului i se aplică o descărcare de 15 kV în aer sau de 8 kV la contact, sistemul CARTO™ 3 afișează 3 mesaje de eroare simultan: Map points cannot be acquired (Nu se pot ob ine punctele de cartografiere - Eroare 401), Patient Body Reference has moved (Referin a corp pacient s-a deplasat - Eroare 256) și o fereastră pop-up care indică modificarea referin ei pentru corpul pacientului. Dacă se produce acest lucru, reporni i PIU.

## DECLARAŢIE DE GARANŢIE ŞI DE LIMITARE A RESPONSABILITĂŢII

**PENTRU PRODUSELE DESCRISE ÎN ACEST DOCUMENT NU SE ACORDĂ NICIUN FEL DE GARANŢIE, IMPLICITĂ SAU EXPLICITĂ, INCLUZÂND, DAR FĂRĂ A SE LIMITA LA, ORICE GARANŢIE IMPLICITĂ PRIVIND VANDABILITATEA PRODUSULUI SAU ADECVAREA ACESTUIA LA UN ANUMIT SCOP. ÎN NICIO CIRCUMSTANŢĂ, BIOSENSE WEBSTER, INC. SAU COMPANIILE SALE AFILIATE NU VOR FI RESPONSABILE PENTRU NICIUN FEL DE DAUNE SPECIALE, DIRECTE, ACCIDENTALE, REZULTATE PE CALE DE CONSECINŢĂ SAU DE ALT TIP, ALTELE DECÂT CELE PREVĂZUTE ÎN MOD EXPRES DE LEGISLAŢIA APLICABILĂ.**

**FĂRĂ LIMITAREA CELOR DE MAI SUS, BIOSENSE WEBSTER, INC. SAU COMPANIILE AFILIATE NU VOR FI RESPONSABILE PENTRU NICIUN FEL DE DAUNE SPECIALE, DIRECTE, ACCIDENTALE, REZULTATE PE CALE DE CONSECINŢĂ SAU DE ALT TIP, DAUNE PRODUSE PRIN REUTILIZAREA ORICĂRUI PRODUS ETICHETAT CA FIIND DE UNICĂ FOLOSINŢĂ SAU ÎN SITUAŢIILE ÎN CARE REUTILIZAREA ESTE INTERZISĂ DE LEGISLAŢIA APLICABILĂ.**

Descrierile şi specifica iile care apar în documenta ia Biosense Webster, Inc. tipărită, inclusiv această publica ie, au numai caracter informativ şi sunt destinate numai descrierii generale a produsului în momentul fabrica iei, nefiind efectuate sau oferite sub nicio formă ca garan ie a produsului prescris.

## INSTRUC IUNI DE UTILIZARE ÎN FORMAT ELECTRONIC

Acest document este disponibil la www.e-ifu.com.

# Кабель TX *eco*

**Предостережение. Федеральный закон (США) допускает продажу данного устройства только лицензированным медицинским специалистам или по их заказу.**

- Не использовать, если упаковка вскрыта или повреждена.

## ОПИСАНИЕ УСТРОЙСТВА

Кабель TX *eco* используется с кабелем-удлинителем для подключения терапевтического катетера Biosense Webster к модулю интерфейса пациента (Patient Interface Unit, PIU) системы CARTO™ 3 (версия 6 и выше). Кабели-удлинители перечислены ниже:

- Для микрокатетера QDOT™: кабель TX *eco* EXT D135703
- Для других терапевтических катетеров Biosense Webster: D128603 (№ по каталогу CR3434CT) или D128604 (№ по каталогу CR3425CT)

Кабель TX *eco* передает данные с терапевтического катетера Biosense Webster в систему CARTO™ 3 и на радиочастотный генератор. Передаваемая информация приведена ниже.

- Сигналы усилия
- Сигналы местоположения
- IC-сигналы от трех микроэлектродов на кончике катетера (только для катетеров с микроэлектродами)
- Измерения температуры от 6 термопар на кончике катетера

## ПОКАЗАНИЯ К ПРИМЕНЕНИЮ

Кабель TX *eco* используется для подключения терапевтического катетера Biosense Webster к модулю интерфейса пациента (PIU) системы CARTO™ 3 (версия 6 и выше).

## ПРЕДУПРЕЖДЕНИЯ

1. Перед использованием этого кабеля ознакомьтесь с *инструкцией по применению* терапевтического катетера Biosense Webster. Если этот кабель будет применяться с модулем QDOT MICRO™, см. *инструкцию по применению* системы CARTO™ 3, а также *инструкцию по применению и примечания к выпуску* для модуля QDOT MICRO™ перед использованием этого кабеля с модулем QDOT MICRO™.
2. Настраивать и использовать этот кабель могут только сотрудники, которые прочли и поняли содержание этого документа.
3. Этот кабель валидирован для использования только с терапевтическим катетером Biosense Webster. Не подключайте этот кабель к любому другому катетеру.
4. Этот кабель предназначен для использования только с терапевтическим катетером Biosense Webster, совместимым радиочастотным генератором, системой CARTO™ 3 и кабелями Biosense Webster. Для получения дополнительной информации обратитесь к представителю компании Biosense Webster.
5. Во время процедуры этот кабель должен находиться на расстоянии не менее 1 метра (39,4 дюйма) от места расположения системы CARTO™ 3.
6. До начала использования этот кабель должен быть подключен к PIU системы CARTO™ 3 для 5-минутного прогрева, чтобы обеспечить точность показаний температуры. После периода прогрева показания температуры стабилизируются. Если кабель используется до окончания периода прогрева, может происходить температурный дрейф.

## УСТАНОВКА КАБЕЛЯ И РАБОТА С НИМ

### Прикрепление держателя кабеля

1. Поместите зажимную часть держателя кабеля (номер детали M652802) на сторону рукоятки тележки системы CARTO™ или поверх поручня кровати. Затем затяните винтовой фиксатор на держателе кабеля.
2. Вставьте кабель в держатель кабеля по направлению вниз.

### Подключение кабеля

1. Подключите красный разъем кабеля к гнезду MAP на модуле PIU системы CARTO™ 3.
2. Подключите желтый разъем кабеля к разъему QUAD B или DECA на модуле PIU.

   Примечание 1. Оба разъема должны быть подключены к модулю PIU.

   Примечание 2. Подключение разъема к гнезду QUAD A может привести к нежелательному шуму на ЭКГ.
3. При использовании микрокатетера QDOT™ подсоедините его к одному концу кабеля TX *eco* EXT. Подсоедините другой конец кабеля TX *eco* EXT к большому гнезду на конце кабеля TX *eco*.
4. При использовании другого терапевтического катетера Biosense Webster подсоедините катетер к одному концу соединительного кабеля. Подсоедините другой конец кабеля-удлинителя к малому круглому гнезду на конце кабеля TX *eco*.

### Отсоединение кабеля

1. Отсоедините красный разъем от модуля PIU системы CARTO™ 3, потянув за разъем, чтобы вытащить его из защелки.
2. Затем отсоедините желтый разъем от модуля PIU, потянув за разъем, чтобы вытащить его из защелки.

   Примечание. Оба разъема должны быть отсоединены от модуля PIU. Не оставляйте один кабель подсоединенным, а другой отсоединенным.
3. После отсоединения кабеля подождите 10 секунд, прежде чем снова подсоединять кабель к модулю PIU.

### Светодиод состояния

Состояние кабеля обозначается светодиодом. После правильного подключения кабеля к PIU системы CARTO™ 3 и к терапевтическому катетеру Biosense Webster кабель выполняет встроенный тест (Built-In Test, BIT).

| Светодиод | Состояние кабеля | Комментарии |
|---|---|---|
| Зеленый: медленно мигает | Выполняется BIT | --- |
| Зеленый: постоянно светится | Готов к использованию | --- |
| Красный: быстро мигает | Ошибка, сбой BIT | Значения температуры не передаются в систему CARTO™ 3 или РЧ-генератор.<br>См. раздел *Поиск и устранение неисправностей* в данном документе. |

## УХОД ЗА КАБЕЛЕМ

### Очистка

Кабель не требует дезинфекции или стерилизации. Не обрабатывайте кабель паром, автоклавированием и не стерилизуйте иным образом.

Если на кабеле появляются пыль или загрязнения, проведите чистку кабеля следующим образом:

1. Отключите кабель.
2. Очистите внешнюю часть кабеля, протерев его салфеткой, смоченной в водном растворе мыла для рук, не содержащего спирта.
3. Следите, чтобы раствор мыла не попал в кабельные разъемы или гнезда.
4. Перед подключением кабеля к системе CARTO™ 3 или к катетеру убедитесь, что кабель сухой.

### Обслуживание

В кабеле нет частей, обслуживание которых может проводить пользователь. Если кабель не работает, обратитесь в службу поддержки клиентов или к представителю компании Biosense Webster для замены. Ожидаемый срок службы кабеля составляет три года.

### Утилизация

Сдавайте на переработку компоненты или утилизируйте изделие и его оставшиеся элементы либо отработанные детали в соответствии с местными законами и нормативами.

## ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ

### Технические параметры

| | |
|---|---|
| **Вход питания постоянного тока** | Кабель получает входную мощность от модуля PIU системы CARTO™ 3. |
| **Масса** | 1 кг (2,2 фунта) |
| **Размеры** | 10 дюймов (длина) x 1,9 дюйма (ширина) x 3 дюйма (высота)<br>(254 мм x 48 мм x 76 мм) |
| **Точность поддержания температуры** | ≤ 2°C |

### Технические параметры эксплуатации, хранения и доставки

| | Минимальное значение | Максимальное значение |
|---|---|---|
| **Условия эксплуатации** | | |
| Внешняя температура | 10 °C | 30 °C |
| Относительная влажность* | 25 % | 75 % |
| **Технические параметры хранения и доставки** | | |
| Внешняя температура | –30 °C | 65 °C |
| Относительная влажность* | 10 % | 95 % |

* В соответствии с требованиями MIL-STD-1695 в месте, где осуществляется работа с электронными деталями и гибридными микросхемами или их обработка, уровни относительной влажности должны находиться в диапазоне 30–70 %. Стандарт MIL-STD-1695 требует того же уровня контроля относительной влажности для зон обращения и хранения, за исключением случаев, когда изделия накрыты или защищены.

### Информация об электромагнитной совместимости

Кабель TX *eco* предназначен для использования в электромагнитной обстановке, характеристики которой указаны в *инструкции по применению* системы CARTO™ 3.

## ПОИСК И УСТРАНЕНИЕ НЕИСПРАВНОСТЕЙ

Если светодиод на кабеле TX *eco* красного цвета и быстро мигает, произошел сбой BIT, который привел к ошибке (см. раздел *Светодиод состояния* этого документа). Выполните следующие действия, чтобы устранить проблему.

1. Отсоедините катетер от кабеля.
2. Отсоедините кабель от модуля PIU системы CARTO™ 3.
3. Снова подсоедините кабель к модулю PIU.
4. Снова подсоедините катетер к кабелю.
5. Если используется модуль QDOT MICRO™, следуйте указаниям в *инструкции по применению и примечаниях к выпуску* для модуля QDOT MICRO™.
6. Если проблема не устранена, обратитесь в службу поддержки клиентов или к представителю компании Biosense Webster.

В некоторых ситуациях, когда на систему CARTO™ 3 подается воздушный разряд 15 кВ или контактный разряд 8 кВ, она одновременно отображает 3 сообщения об ошибках: Map points cannot be acquired (Невозможно выполнить регистрацию картирующих точек) (ошибка 401), Patient Body Reference has moved (Референтное устройство положения тела пациента сместилось) (ошибка 256) и всплывающее сообщение об изменении референтного устройства положения тела пациента. В этом случае перезапустите модуль PIU.

## ОТКАЗ ОТ ГАРАНТИИ И ОГРАНИЧЕНИЕ ОТВЕТСТВЕННОСТИ

**НА ОПИСАННЫЕ В НАСТОЯЩЕМ ДОКУМЕНТЕ ОДНО ИЛИ НЕСКОЛЬКО ИЗДЕЛИЙ НЕ ДАЕТСЯ НИКАКИХ ЯВНЫХ ИЛИ ПОДРАЗУМЕВАЕМЫХ ГАРАНТИЙ, В ТОМ ЧИСЛЕ, БЕЗ ОГРАНИЧЕНИЙ, ЛЮБОЙ ПОДРАЗУМЕВАЕМОЙ ГАРАНТИИ ГОДНОСТИ К ПРОДАЖЕ ИЛИ ПРИГОДНОСТИ К КОНКРЕТНОЙ ЦЕЛИ. НИ ПРИ КАКИХ ОБСТОЯТЕЛЬСТВАХ КОМПАНИЯ BIOSENSE WEBSTER, INC. И ЕЕ ФИЛИАЛЫ НЕ НЕСУТ ОТВЕТСТВЕННОСТЬ ЗА КАКИЕ-ЛИБО ФАКТИЧЕСКИЕ, ПРЯМЫЕ, КОСВЕННЫЕ, ПОБОЧНЫЕ ИЛИ ДРУГИЕ УБЫТКИ, КРОМЕ ЯВНО УКАЗАННЫХ В ПРИМЕНИМОМ ЗАКОНОДАТЕЛЬСТВЕ.**

**БЕЗ ОГРАНИЧЕНИЙ УКАЗАННОГО ВЫШЕ КОМПАНИЯ BIOSENSE WEBSTER, INC. И ЕЕ ФИЛИАЛЫ НЕ БУДУТ НЕСТИ ОТВЕТСТВЕННОСТИ ЗА КАКИЕ-ЛИБО РЕАЛЬНЫЕ, ПРЯМЫЕ, КОСВЕННЫЕ, ПОБОЧНЫЕ И ДРУГИЕ УБЫТКИ, ВЫЗВАННЫЕ ПОВТОРНЫМ ИСПОЛЬЗОВАНИЕМ ЛЮБЫХ ИЗДЕЛИЙ С МАРКИРОВКОЙ «ДЛЯ ОДНОРАЗОВОГО ИСПОЛЬЗОВАНИЯ», ИЛИ ЕСЛИ ПОВТОРНОЕ ИСПОЛЬЗОВАНИЕ ЗАПРЕЩЕНО ДЕЙСТВУЮЩИМ ЗАКОНОДАТЕЛЬСТВОМ.**

Описания и спецификации в печатных публикациях компании Biosense Webster, Inc. включая настоящую публикацию, являются исключительно информационными материалами, в них представлено только общее описание изделия на момент изготовления, и они ни в коей мере не являются гарантией и не выдаются в качестве гарантии на описанное изделие.

## ЭЛЕКТРОННЫЕ ИНСТРУКЦИИ ПО ПРИМЕНЕНИЮ

Данный документ доступен на сайте www.e-ifu.com.

# Kábel TX *eco*

**Pozor: Federálne zákony (USA) obmedzujú predaj tejto pomôcky výlučne licencovanému zdravotníckemu pracovníkovi alebo na jeho predpis.**

- Ak je balenie otvorené alebo poškodené, výrobok nepoužívajte.

## OPIS ZARIADENIA

Kábel TX *eco* sa s predlžovacím káblom používa na pripojenie liečebného katétra Biosense Webster k jednotke rozhrania pacienta (PIU) systému CARTO™ 3 (verzia 6 alebo novšia). Predlžovacie káble sú uvedené nižšie:

- Pre mikrokatéter QDOT™: Kábel TX *eco* EXT D135703
- V prípade iných liečebných katétrov Biosense Webster: D128603 (katalógové č. CR3434CT) alebo D128604 (katalógové č. CR3425CT)

Kábel TX *eco* prenáša údaje z liečebného katétra Biosense Webster do systému CARTO™ 3 a RF generátora. Prenášané údaje sú uvedené nižšie.

- Silové signály
- Signály umiestnenia
- IC signály z 3 mikroelektród v hrote katétra (len pre katétre s mikroelektródami)
- Merania teploty zo 6 termočlánkov v hrote katétra

## INDIKÁCIE NA POUŽITIE

Kábel TX *eco* sa používa na pripojenie liečebného katétra Biosense Webster k jednotke rozhrania pacienta (PIU) systému CARTO™ 3 (verzia 6 alebo novšia).

## VÝSTRAHY

1. Pred použitím tohto kábla si prečítajte *návod na použitie* liečebného katétra Biosense Webster. Ak sa tento kábel používa s modulom QDOT MICRO™, pozrite si *návod na použitie* systému CARTO™ 3 a *návod na použitie a poznámky k vydaniu* modulu QDOT MICRO™ pred tým, ako použijete tento kábel s modulom QDOT MICRO™.
2. Tento kábel môže používať a inštalovať len personál, ktorý si prečítal obsah tohto dokumentu a porozumel mu.
3. Tento kábel je schválený len na použitie s liečebným katétrom Biosense Webster. Tento kábel nepripájajte k žiadnemu inému katétru.
4. Tento kábel slúži len na použitie s liečebným katétrom Biosense Webster, kompatibilným RF generátorom, systémom CARTO™ 3 a káblami od spoločnosti Biosense Webster. Ohľadom podrobností kontaktujte zástupcu spoločnosti Biosense Webster.
5. Tento kábel musí byť počas zákroku aspoň 1 meter (39,4 palca) od polohovej podložky systému CARTO™ 3.
6. Tento kábel musí byť pripojený k jednotke PIU systému CARTO™ 3 na 5-minútové zahrievacie obdobie pred tým, ako sa použije, aby sa zaistili presné merania teploty. Po zahrievacom období budú merania teploty stabilizované. Ak sa kábel použije pred koncom zahrievacieho obdobia, môže dôjsť k posunom teplôt.

## INŠTALÁCIA A PREVÁDZKA KÁBLA

### Pripojenie držiaka kábla

1. Umiestnite svorkovú časť držiaka kábla (číslo dielu M652802) na bočnú stranu rukoväti vozíka systému CARTO™ alebo cez zábranu lôžka. Potom utiahnite gombík na držiaku kábla.
2. Vložte kábel do držiaka kábla tak, aby kábel smeroval nadol.

### Pripojenie kábla

1. Pripojte červený konektor kábla k zásuvke MAP na jednotke PIU systému CARTO™ 3.
2. Pripojte žltý konektor kábla k zásuvke QUAD B alebo DECA na jednotke PIU.

   Poznámka 1: Oba konektory musia byť pripojené k jednotke PIU.

   Poznámka 2: Pripojenie konektora k zásuvke QUAD A môže viesť k nežiaducemu šumu EKG.
3. Ak používate mikro katéter QDOT™, pripojte katéter k jednému koncu kábla TX *eco* EXT. Pripojte druhý koniec kábla TX *eco* EXT k veľkej zásuvke na konci kábla TX *eco*.
4. Ak používate iný liečebný katéter Biosense Webster, pripojte katéter k jednému koncu predlžovacieho kábla. Pripojte druhý koniec predlžovacieho kábla k malej okrúhlej zásuvke na konci kábla TX *eco*.

### Odpojenie kábla

1. Odpojte červený konektor od jednotky PIU systému CARTO™ 3 potiahnutím konektora z upevnenia povoliteľného vysunutím.
2. Potom odpojte žltý konektor od jednotky PIU potiahnutím konektora z upevnenia povoliteľného vysunutím.

   Poznámka: Oba konektory musia byť odpojené od jednotky PIU. Nenechávajte jeden kábel pripojený a druhý odpojený.
3. Po odpojení kábla počkajte 10 sekúnd pred opätovným pripojením kábla k jednotke PIU.

### Stav kontrolky LED

Stav kábla je indikovaný pomocou kontrolky LED. Po správnom pripojení kábla k jednotke PIU systému CARTO™ 3 a liečebnému katétru Biosense Webster vykoná kábel zabudovaný test (BIT).

| LED | Stav kábla | Poznámky |
|---|---|---|
| Zelená: pomalé blikanie | Prebieha test BIT | --- |
| Zelená: svieti | Pripravený na použitie | --- |
| Červená: rýchle blikanie | Chyba, test BIT zlyhal | Teploty nie sú odoslané do systému CARTO™ 3 ani RF generátora.<br>Pozrite si časť *Riešenie problémov* v tomto dokumente. |

## STAROSTLIVOSŤ O KÁBEL

### Čistenie

Kábel nevyžaduje dezinfekciu ani sterilizáciu. Kábel nesterilizujte parou, v autokláve ani iným spôsobom.

Ak sa na káble vyskytnú prach alebo úlomky, vyčistite kábel nasledujúcim spôsobom:

1. Odpojte kábel.
2. Vyčistite vonkajšiu stranu kábla utretím handričkou namočenou v mydle na ruky bez alkoholu a vode.
3. Zaistite, aby do konektorov ani zásuviek kábla nevnikol žiadny mydlový roztok.
4. Pred pripojením kábla k systému CARTO™ 3 alebo ku katétru overte, že je suchý.

### Údržba

V káble sa nenachádzajú žiadne časti, ktoré by mohol používateľ opraviť sám. Ak kábel pri prevádzke zlyhá, obráťte sa na oddelenie zákazníckej podpory alebo zástupcu spoločnosti Biosense Webster ohľadom výmeny. Očakávaná doba použiteľnosti kábla je tri roky.

### Likvidácia

Komponenty recyklujte alebo výrobok a jeho zvyšné časti alebo odpad likvidujte v súlade s miestnymi zákonmi a predpismi.

## TECHNICKÉ ÚDAJE

### Špecifikácie

| | |
|---|---|
| **Vstup jednosmerného prúdu** | Kábel má vstup napájania z jednotky PIU systému CARTO™ 3. |
| **Hmotnosť** | 1 kg (2,2 libry) |
| **Rozmery** | 10 palcov dlhý x 1,9 palca široký x 3 palce vysoký (254 mm x 48 mm x 76 mm) |
| **Presnosť teploty** | ≤ 2 °C |

### Špecifikácie prevádzky, skladovania a prepravy

| | Minimum | Maximum |
|---|---|---|
| **Špecifikácie prevádzky** | | |
| Teplota prostredia | 10 °C | 30 °C |
| Relatívna vlhkosť* | 25 % | 75 % |
| **Špecifikácie skladovania a prepravy** | | |
| Teplota prostredia | -30 °C | 65 °C |
| Relatívna vlhkosť* | 10 % | 95 % |

* V súlade s normou MIL-STD-1695 majú byť úrovne relatívnej vlhkosti v rozsahu 30 % až 70 % v oblastiach, kde sa manipuluje s elektronickými dielmi a hybridnými mikrookruhmi alebo kde sa spracovávajú. Norma MIL-STD-1695 vyžaduje rovnakú úroveň kontrol relatívnej vlhkosti pre oblasti na manipuláciu a skladovanie okrem prípadov, keď sú položky zakryté alebo chránené.

### Informácie o elektromagnetickej kompatibilite

Kábel TX *eco* je určený na použitie v elektromagnetickom prostredí špecifikovanom v *návode na použitie* systému CARTO™ 3.

## RIEŠENIE PROBLÉMOV

Ak je kontrolka LED na káble TX *eco* červená a rýchlo bliká, test BIT zlyhal a spôsobil chybu (pozrite si časť *Stav kontrolky LED* v tomto dokumente). Ak chcete problém vyriešiť, postupujte podľa nižšie uvedených krokov.

1. Odpojte katéter od kábla.
2. Odpojte kábel od jednotky PIU systému CARTO™ 3.
3. Opätovne pripojte kábel k jednotke PIU.
4. Opätovne pripojte katéter ku káblu.
5. Ak sa používa modul QDOT MICRO™, postupujte podľa pokynov v *návode na použitie a poznámkach k vydaniu* pre modul QDOT MICRO™.
6. Ak problém pretrváva, obráťte sa na oddelenie zákazníckej podpory alebo zástupcu spoločnosti Biosense Webster.

V niektorých situáciách, keď je na systém aplikovaný vzduchový výboj 15 kV alebo kontaktný výboj 8 kV, zobrazí systém CARTO™ 3 súčasne 3 chybové hlásenia: Nedajú sa získať mapové body (Chyba 401), Presunula sa referencia tela pacienta (Chyba 256) a vyskakovacie okno, ktoré naznačuje zmenu referencie tela pacienta. Ak nastane táto situácia, reštartujte jednotku PIU.

## VYHLÁSENIE O ZÁRUKE A OBMEDZENEJ ZODPOVEDNOSTI

**NA VÝROBOK POPÍSANÝ V TOMTO DOKUMENTE SA NEPOSKYTUJE ŽIADNA VYSLOVENÁ ALEBO IMPLICITNÁ ZÁRUKA, A TO BEZ OHĽADU NA AKÚKOĽVEK IMPLICITNÚ ZÁRUKU TÝKAJÚCU SA PREDAJNOSTI ALEBO VHODNOSTI NA TEN-KTORÝ ÚČEL. SPOLOČNOSŤ BIOSENSE WEBSTER, INC. ANI JEJ SESTERSKÉ SPOLOČNOSTI ZA ŽIADNYCH OKOLNOSTÍ NEZODPOVEDAJÚ ZA ŽIADNE MIMORIADNE, PRIAME, NEPRIAME ALEBO INÉ ŠKODY OKREM ŠKÔD, KTORÉ VÝSLOVNE URČUJE PRÍSLUŠNÝ ZÁKON.**

**BEZ OBMEDZENIA VYŠŠIE UVEDENÉHO SPOLOČNOSŤ BIOSENSE WEBSTER, INC. ANI JEJ SESTERSKÉ SPOLOČNOSTI NEZODPOVEDAJÚ ZA ŽIADNE MIMORIADNE, PRIAME, NEPRIAME ALEBO INÉ ŠKODY, KTORÉ VZNIKNÚ V DÔSLEDKU OPAKOVANÉHO POUŽITIA VÝROBKU ALEBO VÝROBKOV OZNAČENÝCH NA JEDNORAZOVÉ POUŽITIE ALEBO V PRÍPADOCH, KEĎ JE OPAKOVANÉ POUŽITIE ZAKÁZANÉ ZÁKONOM.**

Popis a vlastnosti uvedené vo vytlačených materiáloch spoločnosti Biosense Webster, Inc. vrátane tejto publikácie majú len informatívny charakter a sú určené len na všeobecný popis výrobku v čase výroby. V žiadnom prípade nepredstavujú ani neposkytujú záruku popisovaného výrobku.

## ELEKTRONICKÝ NÁVOD NA POUŽITIE

Tento dokument je k dispozícii na adrese www.e-ifu.com.

# Kabel TX *eco*

**Pozor: Zvezna zakonodaja (ZDA) predpisuje, da sme to napravo prodajati oz. naročiti le zdravnik z ustrezno licenco.**

- Ne uporabite, če je embalaža odprta ali poškodovana.

## OPIS PRIPOMOČKA

Kabel TX *eco* se uporablja s podaljševalnim kablom za povezovanje terapevtskega katetra Biosense Webster z bolnikovim vmesnikom na sistemu CARTO™ 3 (različica 6 in novejše različice). V nadaljevanju so navedeni podaljševalni kabli:

- za mikrokateter QDOT™: kabel TX *eco* EXT D135703
- za druge terapevtske katetre Biosense Webster: D128603 (kataloška št. CR3434CT) ali D128604 (kataloška št. CR3425CT)

Kabel TX *eco* podatke iz terapevtskega katetra Biosense Webster posreduje v sistem CARTO™ 3 in RF-generator. V nadaljevanju so navedeni podatki, ki se posredujejo:

- signali moči,
- signali lokacije,
- signali IC iz 3 mikroelektrod v konici katetra (velja samo za katetre z mikroelektrodami),
- meritve temperature iz 6 termočlenov v konici katetra.

## INDIKACIJE ZA UPORABO

Kabel TX *eco* se uporablja za povezovanje terapevtskega katetra Biosense Webster z bolnikovim vmesnikom na sistemu CARTO™ 3 (različica 6 in novejše različice).

## OPOZORILA

1. Preden uporabite ta kabel, preberite *navodila za uporabo* terapevtskega katetra Biosense Webster. Če ta kabel uporabljate z modulom QDOT MICRO™, glejte *navodila za uporabo* sistema CARTO™ 3 ter *navodila za uporabo in informacije ob izdaji izdelka* za modul QDOT MICRO™, preden kabel uporabite z modulom QDOT MICRO™.
2. Ta kabel smejo namestiti in uporabljati le osebe, ki so prebrale ta navodila za uporabo in razumejo njihovo vsebino.
3. Ta kabel je potrjen samo za uporabo s terapevtskim katetrom Biosense Webster. Tega kabla ne povezujte z nobenimi drugimi katetri.
4. Ta kabel je namenjen samo za uporabo z združljivim terapevtskim katetrom Biosense Webster, združljivim RF-generatorjem, sistemom CARTO™ 3 in kabli Biosense Webster. O podrobnostih se posvetujte s predstavnikom podjetja Biosense Webster.
5. Ta kabel mora biti med postopkom vsaj 1 meter (39,4 in) oddaljen od lokacijske enote sistema CARTO™ 3.
6. Ta kabel je treba v bolnikov vmesnik sistema CARTO™ 3 priključiti 5 minut pred uporabo, da se ogreje, saj s tem zagotovite točne temperaturne odčitke. Po obdobju ogrevanja se temperaturni odčitki stabilizirajo. Če kabel uporabite pred koncem obdobja ogrevanja, lahko pride do temperaturnega nihanja.

## NAMEŠČANJE IN UPORABA KABLA

### Nameščanje držala za kabel

1. Pritrditveni del držala za kabel (številka dela M652802) namestite na držalo na vozičku sistema CARTO™ ali na posteljno ograjo. Nato privijte gumb na držalu za kabel.
2. Kabel vstavite v držalo za kabel tako, da bo kabel obrnjen navzdol.

### Priključitev kabla

1. Rdeči priključek kabla priključite v vtičnico MAP na bolnikovem vmesniku sistema CARTO™ 3.
2. Rumeni priključek kabla priključite v vtičnico QUAD B ali DECA na bolnikovem vmesniku.

   Opomba 1: oba priključka morata biti priključena v bolnikov vmesnik.

   Opomba 2: priključitev priključka v vtičnico QUAD A lahko sproži neželen šum signala EKG-ja.
3. Če uporabljate mikrokateter QDOT™, kateter priključite na en konec kabla TX *eco* EXT. Drugi konec kabla TX *eco* EXT priključite v veliko vtičnico na koncu kabla TX *eco*.
4. Če uporabljate drug terapevtski kateter Biosense Webster, kateter priključite na en konec podaljševalnega kabla. Drugi konec podaljševalnega kabla priključite v malo okroglo vtičnico na koncu kabla TX *eco*.

### Odklop kabla

1. Rdeči priključek odklopite od bolnikovega vmesnika sistema CARTO™ 3 tako, da priključek izvlečete iz nastavka za drsno sprostitev.
2. Nato odklopite rumeni priključek od bolnikovega vmesnika tako, da priključek izvlečete iz nastavka za drsno sprostitev.

   Opomba: oba priključka morata biti odklopljena iz bolnikovega vmesnika. Ko je en kabel odklopljen, naj drugi ne ostane priključen.
3. Ko kabel odklopite, počakajte 10 sekund, preden ga znova priključite na bolnikov vmesnik.

### Stanje LED

Stanje kabla kaže LED-dioda. Ko je kabel pravilno priključen v bolnikov vmesnik sistema CARTO™ 3 in na terapevtski kateter Biosense Webster, kabel izvede interni preskus (Built-In Test − BIT).

| LED | Stanje kabla | Opombe |
|---|---|---|
| Zelena: počasi utripa | Izvaja se BIT | --- |
| Zelena: sveti | Pripravljeno za uporabo | --- |
| Rdeča: hitro utripa | Napaka, BIT ni uspel | Temperatura se ne pošilja v sistem CARTO™ 3 ali RF-generator.<br>Glejte poglavje *Odpravljanje težav* v tem dokumentu. |

## VZDRŽEVANJE KABLA

### Čiščenje

Kabla ni treba razkuževati ali sterilizirati. Kabla ne sterilizirajte s paro, avtoklaviranjem ali na kakršen koli drugi način.

Če so na kablu ostanki ali prah, kabel očistite na naslednji način:

1. Kabel odklopite.
2. Očistite zunanje površine kabla tako, da jih obrišete s krpo, navlaženo z milom za roke, ki ne vsebuje alkohola, in vodo.
3. Poskrbite, da milnica ne zaide v priključke kabla ali vtičnice.
4. Poskrbite tudi, da je kabel suh, preden ga priključite na sistem CARTO™ 3 ali kateter.

### Vzdrževanje

V kablu ni delov, ki bi jih lahko servisiral uporabnik. Če kabel ne deluje več, se obrnite na podporo za stranke ali predstavnika podjetja Biosense Webster, da vam kabel zamenja. Pričakovana življenjska doba kabla je tri leta.

### Odstranjevanje

Recikliranje sestavnih delov oziroma odlaganje izdelka in njegovih izrabljenih oz. odpadnih delov izvedite v skladu z lokalnimi uredbami in predpisi.

## TEHNIČNI PODATKI

### Specifikacije

| | |
|---|---|
| **Napajanje z enosmernim tokom** | Kabel se napaja preko bolnikovega vmesnika sistema CARTO™ 3. |
| **Teža** | 1 kg (2,2 lb) |
| **Dimenzije** | 10 in (dolžina) x 1,9 in (širina) x 3 in (višina)<br>(254 mm x 48 mm x 76 mm) |
| **Točnost temperature** | ≤ 2 °C |

### Delovni pogoji ter pogoji za shranjevanje in prevoz

| | Najmanj | Največ |
|---|---|---|
| **Specifikacije za upravljanje** | | |
| Temperatura okolja | 10 °C | 30 °C |
| Relativna vlažnost* | 25 % | 75 % |
| **Specifikacije za shranjevanje in prevoz** | | |
| Temperatura okolja | –30 °C | 65 °C |
| Relativna vlažnost* | 10 % | 95 % |

* V skladu s standardom MIL-STD-1695 mora biti raven relativne vlažnosti na mestih, kjer se uporabljajo ali obdelujejo elektronski deli in hibridna mikrovezja, v razponu od 30 do 70 %. Standard MIL-STD-1695 zahteva enako raven nadzora relativne vlažnosti za mesta, kjer se izdelek uporablja in shranjuje, razen če so elementi pokriti oziroma zaščiteni.

### Podatki EMZ

Kabel TX *eco* je predviden za uporabo v elektromagnetnem okolju, opredeljenem v *navodilih za uporabo* sistema CARTO™ 3.

## ODPRAVLJANJE TEŽAV

Če LED-dioda na kablu TX *eco* sveti rdeče in hitro utripa, BIT ni uspel in je povzročil napako (glejte *poglavje Stanje LED* v tem dokumentu). Da odpravite težavo, upoštevajte naslednje korake.

1. Kateter odklopite od kabla.
2. Kabel odklopite iz bolnikovega vmesnika sistema CARTO™ 3.
3. Kabel znova priključite v bolnikov vmesnik.
4. Kateter znova priključite na kabel.
5. Če uporabljate modul QDOT MICRO™, sledite napotkom iz *navodil za uporabo in informacij ob izdaji izdelka* za modul QDOT MICRO™.
6. Če težave niste odpravili, se za pomoč obrnite na podporo za stranke ali na svojega zastopnika podjetja Biosense Webster.

V nekaterih primerih, ko pri sistemu pride do 15-kV razelektritve v zrak ali 8-kV kontaktne razelektritve, sistem CARTO™ 3 istočasno prikaže 3 sporočila o napakah: točk preslikave ni mogoče pridobiti (napaka 401), referenca bolnikovega telesa se je premaknila (napaka 256) in pojavno okno, ki sporoča, da se je referenca bolnikovega telesa premaknila. Če se to zgodi, znova zaženite bolnikov vmesnik.

## IZJAVA O GARANCIJI IN OMEJENI ODGOVORNOSTI

**NE OBSTAJA NOBENO JAMSTVO IZREČENO ALI IMPLICITNO, VKLJUČUJOČ BREZ OMEJITEV KAKRŠNOKOLI IMPLICITNO JAMSTVO O USTREZNOSTI ZA PRODAJO ALI NAMEN ZA OPISAN IZDELEK V TEM OMEJENEM JAMSTVU. BIOSENSE WEBSTER, INC., ALI Z NJIM POVEZANE DRUŽBE, V NOBENEM PRIMERU NE ODGOVARJAJO ZA KAKRŠNOKOLI POSEBNO, NEPOSREDNO, NAKLJUČNO, POSLEDIČNO ALI DRUGAČNO OBLIKO ŠKODE, RAZEN ČE TO NI IZRECNO DOLOČENO S POSEBNIM ZAKONOM.**

**BREZ OMEJITVE GLEDE NA POVEDANO BIOSENSE WEBSTER, INC. IN NJEGOVI LICENČNI PARTNERJI V NOBENEM PRIMERU NE ODGOVARJAJO ZA POSEBNO, DIREKTNO, NAKLJUČNO, POSLEDIČNO ALI DRUGO ŠKODO, KI IZVIRA IZ PONOVNE UPORABE KATEREGAKOLI OD IZDELKOV, KI SO NAMENJENI ENKRATNI UPORABI ALI KJER JE PONOVNA UPORABA PREPOVEDANA Z USTREZNIM ZAKONOM.**

Opisi in specifikacije navedene v tiskanih dokumentih podjetja Biosense Webster, Inc. vključujoč to publikacijo, so zgolj informativni in namenjeni zgolj splošnemu opisu izdelka, v času, ko je bil ta proizveden, in niso v nobenem primeru napisani oz. dani kot jamstvo za predpisan izdelek.

## ELEKTRONSKA NAVODILA ZA UPORABO

Ta dokument je na voljo na www.e-ifu.com.

# TX *eco* кабл

**Опрез: Савезни закон (САД) ограничава продају овог уређаја на продају од стране или по налогу лиценцираног лекара.**

- Не користити ако је паковање отворено или оштећено.

## ОПИС УРЕЂАЈА

TX *eco* кабл се користи са продужним каблом за повезивање Biosense Webster катетера за терапију са интерфејс јединицом за пацијента (PIU) CARTO™ 3 система (верзија 6 и новија). Продужни каблови су наведени у наставку:

- За QDOT™ Micro катетер: TX *eco* EXT кабл D135703
- За друге катетере за терапију компаније Biosense Webster: D128603 (кат. бр. CR3434CT) или D128604 (кат. бр. CR3425CT)

TX *eco* кабл преноси податке са Biosense Webster катетера за терапију у CARTO™ 3 систем и РФ генератор. Информације које се преносе наведене су у наставку.

- Сигнали напрезања
- Сигнали локације
- ИЦ сигнали са 3 микроелектроде у врху катетера (само за катетере са микроелектродама)
- Мерења температуре са 6 термо парова у врху катетера

## ИНДИКАЦИЈЕ ЗА УПОТРЕБУ

TX *eco* кабл се користи за повезивање Biosense Webster катетера за терапију са интерфејс јединицом за пацијента (PIU) CARTO™ 3 система (верзија 6 и новија).

## УПОЗОРЕЊА

1. Пре коришћења овог кабла прочитајте *Упутство за употребу* Biosense Webster катетера за терапију. Ако се овај кабл користи са QDOT MICRO™ модулом, погледајте *Упутство за употребу* за CARTO™ 3 систем и *Упутство за употребу и напомене о верзији* за QDOT MICRO™ модул пре коришћења овог кабла са QDOT MICRO™ модулом.
2. Само чланови особља који су прочитали и разумели садржај овог документа смеју да постављају и користе овај кабл.
3. Овај кабл је проверен само за коришћење са Biosense Webster катетером за терапију. Немојте да повезујете овај кабл са било којим другим катетером.
4. Овај кабл је предвиђен за употребу само са Biosense Webster катетером за терапију, компатибилним РФ генератором, системом CARTO™ 3 и Biosense Webster кабловима. Детаље потражите од вашег представника компаније Biosense Webster.
5. Овај кабл мора да буде удаљен најмање 1 метар (39,4 in) од локационе табле CARTO™ 3 система током поступка.
6. Да би се осигурала прецизна очитавања температуре, овај кабл мора пре коришћења да се повеже са интерфејс јединицом за пацијента система CARTO™ 3 ради загревања од 5 минута. Након периода загревања, очитавања температуре се стабилизују. Ако се кабл употреби пре истека периода загревања, може доћи до одступања температуре.

## ИНСТАЛИРАЊЕ И РАД СА КАБЛОМ

### Причвршћивање држача кабла

1. Поставите стезни део држача кабла (каталошки број M652802) на страни дршке колица CARTO™ система или преко шипке кревета. Затим затегните дугме на држачу кабла.
2. Уметните кабл у држач кабла тако да кабл буде окренут надоле.

### Повезивање кабла

1. Повежите црвени конектор кабла на MAP утичницу интерфејс јединице за пацијента CARTO™ 3 система.
2. Повежите жути конектор кабла на QUAD B или DECA утичницу интерфејс јединице за пацијента.

   Напомена 1: Оба конектора морају бити повезана на интерфејс јединицу за пацијента.

   Напомена 2: Повезивање конектора на QUAD A може да доведе до нежељеног ЕКГ шума.
3. Ако користите QDOT™ Micro катетер, повежите катетер са једним крајем кабла TX *eco* EXT. Прикључите други крај TX *eco* EXT кабла у велику утичницу на другом крају кабла TX *eco*.
4. Ако користите други катетер за терапију компаније Biosense Webster, повежите катетер са једним крајем продужног кабла. Прикључите други крај продужног кабла у малу округлу утичницу на другом крају кабла TX *eco*.

### Одвајање кабла

1. Одвојите црвени конектор са интерфејс јединице за пацијента CARTO™ 3 система повлачењем конектора из клизне стеге за ослобађање.
2. Затим одвојите жути конектор са интерфејс јединице за пацијента повлачењем конектора из клизне стеге за ослобађање.

   Напомена: Оба конектора морају бити одвојена од интерфејс јединице за пацијента. Немојте да остављате један кабл повезан док је други одвојен.
3. Након одвајања кабла, сачекајте 10 секунди пре него што поново повежете кабл са интерфејс јединицом за пацијента.

### Статусна ЛЕД диода

Статус кабла се сигнализира ЛЕД диодом. Када се кабл правилно повеже са интерфејс јединицом за пацијента CARTO™ 3 система и Biosense Webster катетер за терапију, кабл обавља интегрисани тест (BIT).

| ЛЕД диода | Статус кабла | Коментари |
|---|---|---|
| Зелена: споро трепери | Интегрисани тест у току | --- |
| Зелена: непрекидно светли | Спреман за употребу | --- |
| Црвена: брзо трепери | Грешка, неуспешан интегрисани тест | Температуре се не шаљу у CARTO™ 3 систем или РФ генератор.<br>Погледајте одељак *Решавање проблема* у овом документу. |

## НЕГА КАБЛА

### Чишћење

Кабл не захтева дезинфекцију или стерилизацију. Кабл не стерилисати паром, аутоклавом или на друге начине.

Ако се на каблу појави прашина или талог, очистите кабл на следећи начин:

1. Одвојите кабл.
2. Спољну површину кабла очистите брисањем крпом која је натопљена средством за прање руку које не садржи алкохол и водом.
3. Постарајте се да сапуница не уђе у прикључке или утичнице кабла.
4. Побрините се да кабл буде сув пре него што га повежете на CARTO™ 3 систем или катетер.

### Одржавање

Кабл не садржи делове које би могао да сервисира корисник. Ако кабл не функционише правилно, обратите се корисничкој подршци или вашем представнику компаније Biosense Webster ради замене. Очекивани корисни век трајања кабла је три године.

### Одлагање

Рециклирајте компоненте или одложите у отпад производ и његове преостале елементе или отпадне делове у складу са локалним законима и прописима.

## ТЕХНИЧКИ ПОДАЦИ

### Спецификације

| | |
|---|---|
| **Улаз једносмерне струје** | Овај кабл се електрично напаја преко интерфејс јединице за пацијента система CARTO™ 3. |
| **Тежина** | 1 кг (2,2 lb) |
| **Димензије** | дужина 10 ин. x ширина 1,9 ин. x висина 3 ин.<br>(254 мм x 48 мм x 76 мм) |
| **Прецизност температуре** | ≤2 °C |

### Спецификације за рад, складиштење и транспорт

| | Минимално | Максимално |
|---|---|---|
| **Радне спецификације** | | |
| Амбијентална температура | 10 °C | 30 °C |
| Релативна влажност* | 25% | 75% |
| **Спецификације за складиштење и транспорт** | | |
| Амбијентална температура | -30 °C | 65 °C |
| Релативна влажност* | 10% | 95% |

* У складу са MIL-STD-1695, нивои релативне влажности биће у опсегу од 30% до 70% у подручјима у којима се рукује електронским деловима и хибридним микроколима или у којима се они обрађују. MIL-STD-1695 захтева исте контроле нивоа релативне влажности за подручја руковања и складиштења, осим када су компоненте покривене или заштићене.

### Информације о електромагнетској компатибилности

TX *eco* кабл је предвиђен за употребу у електромагнетском окружењу као што је наведено у *Упутству за употребу* CARTO™ 3 система.

## РЕШАВАЊЕ ПРОБЛЕМА

Ако је ЛЕД диода на TX *eco* каблу црвене боје и брзо трепери, интегрисани тест није успео и узроковао је грешку (погледајте одељак *Статусна ЛЕД диода* у овом документу). Пратите кораке у наставку да бисте решили проблем.

1. Одвојите катетер од кабла.
2. Одвојите кабл са интерфејс јединице за пацијента CARTO™ 3 система.
3. Поново повежите кабл на интерфејс јединицу за пацијента.
4. Поново повежите катетер са каблом.
5. Ако се користи QDOT MICRO™ модул, пратите смернице наведене у *Упутству за употребу и напоменама о верзији* за QDOT MICRO™ модул.
6. Ако се проблем настави, обратите се служби за кориснике или представнику компаније Biosense Webster.

У неким ситуацијама, када се на систем примени пражњење путем ваздуха од 15 kV или пражњење путем контакта од 8 kV, CARTO™ 3 систем истовремено приказује 3 поруке о грешци: није могуће прибавити тачке мапе (Грешка 401), референца тела пацијента је померена (Грешка 256) и искачућа порука која означава промену референце тела пацијента. Ако до овога дође, рестартујте интерфејс јединице за пацијента.

## ОДРИЦАЊЕ ГАРАНЦИЈЕ И ОГРАНИЧЕЊЕ ОДГОВОРНОСТИ

**НЕМА ИЗРИЧИТЕ ИЛИ ИМПЛИЦИРАНЕ ГАРАНЦИЈЕ, УКЉУЧУЈУЋИ БЕЗ ОГРАНИЧЕЊА СВАКУ ИМПЛИЦИРАНУ ГАРАНЦИЈУ ПОДЕСНОСТИ ЗА ТРГОВИНУ ИЛИ ПОГОДНОСТИ ЗА ОДРЕЂЕНУ НАМЕНУ, ЗА ПРОИЗВОД(Е) ОПИСАНЕ У ОВОМ ТЕКСТУ. НИ ПОД КОЈИМ ОКОЛНОСТИМА КОМПАНИЈА BIOSENSE WEBSTER, INC. ИЛИ ЊЕНЕ ПОВЕЗАНЕ КОМПАНИЈЕ НЕЋЕ БИТИ ОДГОВОРНА ЗА БИЛО КОЈЕ СПЕЦИЈАЛНЕ, ДИРЕКТНЕ, СЛУЧАЈНЕ, ПОСЛЕДИШТЕ ИЛИ ДРУГЕ ШТЕТЕ, ОСИМ ОНИХ КОЈЕ СУ ИЗРИЧИТО ОДРЕЂЕНЕ ВАЖЕЋИМ ЗАКОНОМ.**

**БЕЗ ОГРАНИЧАВАЊА НАВЕДЕНОГ, BIOSENSE WEBSTER, INC. ИЛИ ЊЕНЕ ПАРТНЕРСКЕ КОМПАНИЈЕ НЕЋЕ БИТИ ОДГОВОРНЕ ЗА БИЛО КАКВУ ПОСЕБНУ, ДИРЕКТНУ, СЛУЧАЈНУ ИЛИ ПОСЛЕДИЧНУ ИЛИ БИЛО КАКВУ ДРУГУ ШТЕТУ НАСТАЛУ УСЛЕД ПОНОВНЕ УПОТРЕБЕ БИЛО КОГ/КОЈИХ ПРОИЗВОДА СА ОЗНАКОМ ЗА ЈЕДНОКРАТНУ УПОТРЕБУ ИЛИ УКОЛИКО ПОНОВНУ УПОТРЕБУ ЗАБРАЊУЈЕ ВАЖЕЋИ ЗАКОН.**

Описи и спецификације који се налазе у штампаном материјалу компаније Biosense Webster, Inc., укључујући и ову публикацију, намењени су искључиво за информативне сврхе и само за општи опис производа у тренутку производње и не пружају се као гаранција за прописани производ ни на који начин.

## ЕЛЕКТРОНСКО УПУТСТВО ЗА УПОТРЕБУ

Овај документ је доступан на интернет адреси www.e-ifu.com.

# TX *eco*-kabel

**Varning: Enligt federal lagstiftning (USA) får denna produkt endast säljas av eller på ordination av en legitimerad läkare.**

- Får ej användas om förpackningen är öppnad eller skadad.

## PRODUKTBESKRIVNING

TX *eco* -kabeln används tillsammans med en förlängningskabel för att ansluta en Biosense Webster terapeutisk kateter till patientgränssnittsenheten (PIU) i CARTO™ 3 System (Version 6 och senare). Förlängningskablarna anges nedan:

- För QDOT™ Micro Catheter: TX *eco* EXT-kabel D135703
- För andra Biosense Webster behandlingskatetrar: D128603 (katalognr CR3434CT) eller D128604 (katalognr CR3425CT)

TX *eco* -kabeln överför data från en Biosense Webster terapeutisk kateter till CARTO™ 3-systemet och RF-generatorn. Den information som överförs anges nedan.

- Kraftsignaler
- Platssignaler
- IC-signaler från de 3 mikroelektroderna i kateterspetsen (endast för katetrar med mikroelektroder)
- Temperaturmätningar från de 6 termoelementen i kateterspetsen

## BRUKSANVISNING

TX *eco* -kabeln används för att ansluta en terapeutisk kateter från Biosense Webster till patientgränssnittsenheten (PIU) i CARTO™ 3 System (Version 6 och senare).

## VARNINGAR

1. Innan du använder den här kabeln ska du läsa följande *Bruksanvisning* för Biosense Webster terapeutisk kateter. Om denna kabel används med QDOT MICRO™-modulen ska *bruksanvisningen* till CARTO™ 3-systemet samt *bruksanvisningen och versionsinformationen* som gäller QDOT MICRO™-modulen läsas innan denna kabel används med QDOT MICRO™-modulen.
2. Endast personal som har läst och förstått innehållet i det här dokumentet får ställa in och använda denna kabel.
3. Denna kabel har endast godkänts för användning med Biosense Webster behandlingskateter. Anslut inte denna kabel till någon annan kateter.
4. Denna kabel är endast avsedd att användas med en Biosense Webster behandlingskateter, en kompatibel RF-generator, ett CARTO™ 3-system och Biosense Webster-kablar. Kontakta din Biosense Webster-representant om du behöver mer information.
5. Kabeln måste vara minst 1 meter (39,4 tum) bort från CARTO™ 3-systemet under förfarandet.
6. Före användning måste denna kabel anslutas till CARTO™ 3-systemets PIU för en 5 minuter lång uppvärmning för att exakta temperaturavläsningar ska kunna garanteras. Efter uppvärmningsperioden stabiliseras temperaturavläsningarna. Om kabeln används innan uppvärmningen har slutförts kan temperaturdrift förekomma.

## INSTALLERA OCH ANVÄNDA KABELN

### Sätta fast kabelhållaren

1. Placera kabelhållarens klämdel (artikelnummer M652802) på sidan av CARTO™-systemets vagnhandtag eller över sängräcket. Dra åt vredet på kabelhållaren.
2. Sätt in kabeln i kabelhållaren med kabeln vänd nedåt.

### Ansluta kabeln

1. Anslut kabelns röda kontakt till MAP-uttaget på CARTO™ 3-systemets PIU.
2. Anslut kabelns gula kontakt till QUAD B- eller DECA-uttaget på PIU:n.

   Obs 1! Båda kontakterna måste anslutas till PIU:n.

   Obs 2! Anslutning av kontakten till QUAD A kan leda till oönskat EKG-brus.
3. Om du använder en QDOT™-mikrokateter ansluter du katetern till den ena änden av TX *eco* EXT -kabeln. Anslut den andra änden av TX *eco* EXT -kabeln till det stora uttaget i slutet av TX *eco* -kabeln.
4. Om en annan Biosense Webster-behandlingskateter används ska katetern anslutas till ena änden av förlängningskabeln. Anslut den andra änden av förlängningskabeln till det lilla runda uttaget i slutet av TX *eco* -kabeln.

### Koppla från kabeln

1. Koppla bort den röda kontakten från CARTO™ 3-systemets PIU genom att dra i kontaktens gliddel.
2. Koppla sedan bort den gula kontakten från PIU:n genom att dra i kontaktens gliddel.

   Obs! Båda kontakterna måste vara bortkopplade från PIU:n. Lämna inte den ena kabeln ansluten och den andra kabeln frånkopplad.
3. Efter att kabeln kopplats från, vänta 10 sekunder innan du återansluter kabeln till PIU:n.

### Lysdiodstatus

Kabelns status anges av en lysdiod. När kabeln är korrekt ansluten till PIU:n på CARTO™ 3-systemet och till Biosense Webster terapeutisk kateter utför den ett inbyggt test (BIT).

| Lysdiod | Kabelstatus | Kommentarer |
|---|---|---|
| Grön: blinkar långsamt | Det inbyggda testet pågår | --- |
| Grön: lyser med ett fast sken | Redo att användas | --- |
| Röd: blinkar snabbt | Fel, det inbyggda testet misslyckades | Temperaturerna skickas inte till CARTO™ 3-systemet eller RF -generatorn.<br>Se avsnittet *Felsökning* i det här dokumentet. |

## KABELSKÖTSEL

### Rengöring

Kabeln kräver ingen desinfektion eller sterilisering. Kabeln får inte ångrengöras, autoklaveras eller på annat sätt steriliseras.

Rengör kabeln på följande sätt om den blir dammig eller smutsig:

1. Koppla från kabeln.
2. Rengör kabelns utsida genom att torka av den med en trasa som är fuktad med alkoholfri handtvål och vatten.
3. Se till att tvållösningen inte tränger in i kabelns kontakter eller uttag.
4. Kontrollera att kabeln är torr innan den ansluts till CARTO™ 3-systemet eller till en kateter.

### Underhåll

Inga delar av kabeln får servas av användaren. Om kabeln inte fungerar kontaktar du kundtjänst eller Biosense Webster-representanten och begär en ny. Kabelns förväntade livslängd är tre år.

### Kassering

Återvinn komponenter eller kassera produkten med kvarstående element eller avfallsartiklar i enlighet med lokala lagar och förordningar.

## TEKNISKA DATA

### Specifikationer

| | |
|---|---|
| **Ingång för likström** | Kabeln får ström från CARTO™ 3-systemets PIU. |
| **Vikt** | 1 kg (2,2 pund) |
| **Mått** | 10 tum lång x 1,9 tum bred x 3 tum hög<br>(254 mm x 48 mm x 76 mm) |
| **Temperaturnogrannhet** | ≤ 2 °C |

### Specifikationer för drift, förvaring och transport

| | Minimum | Maximum |
|---|---|---|
| **Driftsspecifikationer** | | |
| Omgivningstemperatur | 10 °C | 30 °C |
| Relativ luftfuktighet* | 25 % | 75 % |
| **Förvarings- och transportspecifikationer** | | |
| Omgivningstemperatur | –30 °C | 65 °C |
| Relativ luftfuktighet* | 10 % | 95 % |

* I enlighet med MIL-STD-1695 ska nivåerna av relativ luftfuktighet ligga inom intervallet 30–70 % på platser där elektroniska delar och hybridmikrokretsar hanteras eller bearbetas. I MIL-STD-1695 krävs samma nivå av reglering av relativ luftfuktighet för hanterings- och förvaringsplatser, såvida inte föremålen är täckta eller skyddade.

### EMC-information

TX *eco* -kabeln är avsedd att användas i en sådan elektromagnetisk miljö som anges i *bruksanvisningen* till CARTO™ 3-systemet.

## FELSÖKNING

Om lysdioden på TX *eco* -kabeln är röd och blinkar snabbt har det inbyggda testet misslyckats och orsakat ett fel (se avsnittet *Lysdiodstatus* i det här dokumentet). Följ stegen nedan för att korrigera problemet.

1. Koppla bort katetern från kabeln.
2. Koppla bort kabeln från CARTO™ 3-systemets PIU.
3. Återanslut kabeln till PIU:n.
4. Återanslut katetern till kabeln.
5. Om en QDOT MICRO™-modul används följer du *bruksanvisningen och den viktiga informationen* gällande QDOT MICRO™-modulen.
6. Om problemet kvarstår, kontakta kundtjänst eller din Biosense Webster-butik.

I vissa situationer, då systemet utsätts för en 15 kV lufturladdning eller en 8 kV kontakturladdning, visar CARTO™ 3-systemet 3 felmeddelanden på samma gång: Ingen åtkomst till Map-punkter (felkod 401), Referensen för patientkroppen har flyttats (felkod 256) samt ett popup-meddelande som anger referensändringen för patientkroppen. Starta om PIU:n om detta inträffar.

## FRISKRIVNING OCH ANSVARSBEGRÄNSNINGAR

**INGEN UTTRYCKT ELLER UNDERFÖRSTÅDD GARANTI UTFÄRDAS, INKLUSIVE, MEN INTE BEGRÄNSAT TILL, UNDERFÖRSTÅDD GARANTI ANGÅENDE SÄLJBARHET ELLER LÄMPLIGHET FÖR ETT VISST SYFTE FÖR PRODUKTEN/PRODUKTERNA SOM BESKRIVS I DETTA DOKUMENT. UNDER INGA OMSTÄNDIGHETER SKALL BIOSENSE WEBSTER, INC., ELLER DESS DOTTERBOLAG, HÅLLAS ANSVARIGA FÖR SPECIELLA, DIREKTA, TILLFÄLLIGA SKADOR ELLER FÖLJDSKADOR, ELLER ANDRA SKADOR ÄN DE SOM UTTRYCKLIGEN SPECIFICERAS I GÄLLANDE LAG.**

**UTAN ATT BEGRÄNSA DET OVANNÄMNDA, SKALL BIOSENSE WEBSTER, INC. OCH DESS DOTTERBOLAG, INTE HÅLLAS ANSVARIGA FÖR SPECIELLA, DIREKTA, TILLFÄLLIGA SKADOR ELLER FÖLJDSKADOR, ELLER ANDRA SKADOR SOM UPPSTÅR PÅ GRUND AV ÅTERANVÄNDNING AV EN ELLER FLERA PRODUKTER VARS ETIKETT ANGER ENGÅNGSANVÄNDNING, OCH DÄR ÅTERANVÄNDNING FÖRBJUDS AV GÄLLANDE LAG.**

Beskrivningar och specifikationer i tryckt material publicerat av Biosense Webster, Inc., inklusive denna publikation, utfärdas endast i informationssyfte, och är endast avsedda att generellt beskriva katetern vid tillverkningstidpunkten och är inte avsedda att utgöra garanti av den ordinerade katetern på något som helst sätt.

## ELEKTRONISK BRUKSANVISNING

Detta dokument finns tillgängligt på www.e-ifu.com.

# TX *eco* Kablo

**Dikkat: Federal yasalar (ABD) uyarınca bu cihaz sadece lisanslı bir sağlık uzmanı tarafından ya da sağlık uzmanının isteği üzerine satılabilir.**

- Ambalaj açılmış ya da zarar görmüşse kullanmayın.

## CİHAZ TANIMI

TX *eco* Kablo, Biosense Webster terapötik kateteri CARTO™ 3 Sisteminin (Versiyon 6 ve üzeri) Hasta Arayüz Ünitesine (PIU) bağlamak için uzatma kablosu ile birlikte kullanılır. Uzatma kabloları aşağıda listelenmiştir:

- QDOT™ Mikro Kateter için: TX *eco* EXT Kablo D135703
- Diğer Biosense Webster terapötik kateterler için: D128603 (katalog no. CR3434CT) veya D128604 (katalog no. CR3425CT)

TX *eco* Kablo, Biosense Webster terapötik kateterden CARTO™ 3 Sistemine ve RF Jeneratörüne veri iletir. İletilen bilgiler aşağıda listelenmiştir.

- Güç sinyalleri
- Konum sinyalleri
- Kateterin ucundaki 3 mikroelektrottan gelen IC sinyalleri (yalnızca mikroelektrotları olan kateterler için)
- Kateterin ucundaki 6 termokupldan gelen sıcaklık ölçümleri

## KULLANIM ENDİKASYONLARI

TX *eco* Kablo, bir Biosense Webster terapötik kateteri CARTO™ 3 Sisteminin (Versiyon 6 ve üzeri) Hasta Arayüz Ünitesine (PIU) bağlamak için kullanılır.

## UYARILAR

1. Bu kabloyu kullanmadan önce Biosense Webster terapötik kateterin *Kullanma Talimatlarını* okuyun. Bu kablo QDOT MICRO™ Modülü ile birlikte kullanılacaksa bu kabloyu QDOT MICRO™ Modülü ile birlikte kullanmadan önce CARTO™ 3 Sisteminin *Kullanma Talimatlarına* ve QDOT MICRO™ Modülünün *Kullanma Talimatları ve Sürüm Notlarına* başvurun.
2. Yalnızca bu belgeyi okuyan ve anlayan personel bu kabloyu takıp kullanabilir.
3. Bu kablo yalnızca bir Biosense Webster terapötik kateter ile kullanım için doğrulanmıştır. Bu kabloyu başka bir katetere bağlamayın.
4. Bu kablonun yalnızca bir Biosense Webster terapötik kateter, uyumlu bir RF jeneratörü, bir CARTO™ 3 Sistemi ve Biosense Webster kabloları ile birlikte kullanılması amaçlanmıştır. Ayrıntılar için Biosense Webster temsilcinize danışın.
5. Bu kablo, prosedür sırasında CARTO™ 3 Sisteminin konum pedinden en az 1 metre (39,4 inç) uzakta olmalıdır.
6. Doğru sıcaklık ölçümleri sağlamak için bu kablo, kullanımdan önce 5 dakikalık bir ısınma süresi boyunca CARTO™ 3 Sisteminin PIU'suna bağlı olmalıdır. Isınma süresinden sonra sıcaklık ölçümleri stabilize olur. Kablo, ısınma süresi bitmeden kullanılırsa bir sıcaklık sapması meydana gelebilir.

## KABLOYU TAKMA VE ÇALIŞTIRMA

### Kablo Tutucuyu Takma

1. Kablo tutucunun kelepçe kısmını (parça numarası M652802), CARTO™ Sistemi Araba tutamağının yan tarafına veya yatak çerçevesine yerleştirin. Ardından kablo tutucudaki düğmeyi sıkın.
2. Kabloyu, aşağı bakacak şekilde kablo tutucuya yerleştirin.

### Kabloyu Bağlama

1. Kablonun kırmızı konnektörünü CARTO™ 3 Sistemi PIU'sunun MAP yuvasına bağlayın.
2. Kablonun sarı konnektörünü PIU'daki QUAD B ve DECA yuvasına bağlayın.

   Not 1: Her iki konnektör de PIU'ya bağlı olmalıdır.

   Not 2: Konnektörü QUAD A'ya bağlamak, istenmeyen EKG parazitine neden olabilir.
3. QDOT™ Mikro Kateter kullanılıyorsa kateteri, TX *eco* EXT Kablonun bir ucuna bağlayın. TX *eco* EXT Kablonun diğer ucunu TX *eco* Kablonun ucundaki büyük yuvaya bağlayın.
4. Başka bir Biosense Webster terapötik kateter kullanıyorsa kateteri uzatma kablosunun bir ucuna bağlayın. Uzatma kablosunun diğer ucunu, TX *eco* Kablonun ucundaki küçük yuvarlak yuvaya bağlayın.

### Kabloyu Çıkarma

1. Konnektörü kaydırmalı serbest bırakma sapından çekerek kırmızı konnektörü CARTO™ 3 Sistemi PIU'sundan çıkarın.
2. Ardından, sarı konnektörü kaydırmalı serbest bırakma sapından çekerek PIU'dan çıkarın.

   Not: Her iki konnektör de PIU'dan çıkarılmalıdır. Bir kabloyu takılı diğerini ise çıkartılmış biçimde bırakmayın.
3. Kabloyu çıkardıktan sonra kabloyu tekrar PIU'ya bağlamadan önce 10 saniye bekleyin.

### LED Durumu

Kablonun durumu bir LED ile gösterilir. Kablo CARTO™ 3 Sistemi PIU'suna ve Biosense Webster terapötik katetere doğru şekilde bağlandıktan sonra kablo, Yerleşik Test (BIT) gerçekleştirir.

| LED | Kablo Durumu | Yorumlar |
|---|---|---|
| Yeşil: yavaş yanıp sönme | BIT devam ediyor | --- |
| Yeşil: sürekli | Kullanıma hazır | --- |
| Kırmızı: hızlı yanıp sönme | Hata, BIT başarısız | Sıcaklıklar CARTO™ 3 Sistemine veya RF jeneratörüne gönderilmiyor.<br>Bu belgenin *Sorun Giderme* bölümüne bakın. |

## KABLO BAKIMI

### Temizlik

Kablo, dezenfeksiyon veya sterilizasyon gerektirmez. Kabloyu buharla sterilize etmeyin, otoklavlamayın veya başka bir şekilde sterilize etmeyin.

Kabloda toz veya birikinti görürseniz kabloyu şu şekilde temizleyin:

1. Kablonun bağlantısını kesin.
2. Alkolsüz el sabunu ve su ile nemlendirilmiş bir bez yardımıyla silerek kablonun dışını temizleyin.
3. Sabunlu çözeltinin kablo konnektörlerine veya yuvalara gelmediğinden emin olun.
4. CARTO™ 3 Sistemine veya bir katetere bağlamadan önce kablonun kuru olduğundan emin olun.

### Bakım

Kablonun kullanıcı tarafından servis uygulanabilecek hiçbir parçası yoktur. Kablo çalışmazsa değiştirilmesi için Müşteri Desteği veya Biosense Webster temsilcinizle iletişime geçin. Kablonun beklenen faydalı kullanım ömrü üç yıldır.

### Atma

Bileşenleri geri dönüştürün veya ürünü ve rezidüel parçalarını veya atık maddelerini yerel kanunlar ve yönetmelikler doğrultusunda atın

## TEKNİK VERİLER

### Spesifikasyonlar

| | |
|---|---|
| **DC Girişi** | Kablo, CARTO™ 3 Sistemi PIU'sunun güç girişinden güç alır. |
| **Ağırlık** | 1 kg (2,2 lb) |
| **Boyutlar** | 10 inç uzunluk x 1,9 inç genişlik x 3 inç yükseklik (254 mm x 48 mm x 76 mm) |
| **Sıcaklık Doğruluğu** | ≤ 2 °C |

### Çalıştırma, Saklama ve Nakliye Spesifikasyonları

| | Minimum | Maksimum |
|---|---|---|
| **Çalıştırma Spesifikasyonları** | | |
| Ortam Sıcaklığı | 10 °C | 30 °C |
| Bağıl nem* | %25 | %75 |
| **Saklama ve Nakliye Spesifikasyonları** | | |
| Ortam Sıcaklığı | -30 °C | 65 °C |
| Bağıl nem* | %10 | %95 |

* MIL-STD-1695'e göre, elektronik parçaların ve hibrit mikrodevrelerin kullanıldığı veya işlendiği alanlarda bağıl nem düzeyleri %30 - %70 arasında olmalıdır. MIL-STD-1695, öğelerin kaplanmış veya korunmuş olduğu durumlar dışında kullanma ve saklama alanları için aynı düzeyde bağıl nem kontrolü gerektirir.

### EMC Bilgisi

TX *eco* Kablonun, CARTO™ 3 Sisteminin *Kullanma Talimatlarında* belirtilen elektromanyetik ortamda kullanılması amaçlanmıştır.

## SORUN GİDERME

TX *eco* Kablo üzerindeki LED kırmızı renkte hızlı şekilde yanıp sönüyorsa, BIT başarısız olmuş ve bir hataya neden olmuştur (bu belgedeki *LED Durumu* bölümüne bakın). Sorunu düzeltmek için aşağıdaki adımları uygulayın.

1. Kateterin kabloyla olan bağlantısını kesin.
2. Kabloyu CARTO™ 3 Sisteminin PIU'sundan çıkarın.
3. Kabloyu PIU'ya yeniden bağlayın.
4. Kateteri kabloya yeniden bağlayın.
5. Bir QDOT MICRO™ Modülü kullanılıyorsa, QDOT MICRO™ Modülünün *Kullanma Talimatlarında ve Sürüm Notlarında* verilen talimatları takip edin.
6. Sorun devam ederse Müşteri Desteği veya Biosense Webster temsilciniz ile iletişime geçin.

Sisteme 15 kV hava deşarjının veya 8 kV temas deşarjının uygulandığı bazı durumlarda CARTO™ 3 Sistemi eş zamanlı olarak 3 hata mesajı görüntüler: Harita noktaları alınamıyor (Hata 401), Hasta Vücut Referansı taşındı (Hata 256) ve Hasta Vücut Referansı değişikliğini belirten bir açılır mesaj. Böyle bir durumda PIU'yu yeniden başlatın.

## GARANTİ REDDİ VE YÜKÜMLÜLÜK KISITLAMASI

**BURADA TANIMLANAN ÜRÜN(LER) İÇİN, SATILABİLİRLİK VE HERHANGİ BİR AMACA UYGUNLUK AÇISINDAN İMA EDİLEN GARANTİLER DAHİL, HERHANGİ BİR KISITLAMA OLMAKSIZIN HİÇBİR İFADE VEYA İMA EDİLMİŞ GARANTİ YOKTUR. HİÇBİR KOŞULDA BIOSENSE WEBSTER, INC. VEYA BAĞLI ŞİRKETLERİ, KANUNLAR TARAFINDAN AÇIKÇA BELİRTİLENLER DIŞINDA HİÇBİR ÖZEL, DOĞRUDAN, DOLAYLI, RİSKE BAĞLI VEYA DİĞER HASARDAN SORUMLU DEĞİLDİR.**

**YUKARIDAKİLERİ KISITLAMADAN, BIOSENSE WEBSTER, INC. VEYA YAN KURULUŞLARI TEK KULLANIM İÇİN ETİKETLENMİŞ ÜRÜNÜN/ÜRÜNLERİN TEKRAR KULLANIMINDAN DOLAYI VEYA İLGİLİ KANUNUN TEKRAR KULLANIMI YASAKLADIĞI DURUMLARDA HERHANGİ BİR ÖZEL, DOĞRUDAN, ARIZİ, ZIMNİ VEYA BAŞKA HASARDAN SORUMLU OLMAYACAKTIR.**

Bu belge dahil olmak üzere Biosense Webster, Inc. yazılı materyalinde bulunan tanımlar ve spesifikasyonlar sadece bilgi vermek ve ürünün üretim tarihindeki durumunu genel olarak tanımlamak amaçlıdır ve reçetelendirilen ürün açısından herhangi bir garanti sağlamak amacıyla hazırlanmazlar ve sunulmazlar.

## ELEKTRONİK KULLANIM TALİMATLARI

Bu belge www.e-ifu.com adresinde mevcuttur.

# TX *eco* 缆线

**注意：美国联邦法律限定本产品只能由持照的医疗从业者销售或凭其医嘱销售。**

- 如果包装打开或破损，请勿使用。

## 产品描

TX *eco* 缆线与延长缆线搭配使用，将 Biosense Webster 治疗导管连接到 CARTO™ 3 系统（版本 6 及更高版本）的患者接口单元（PIU）。延长缆线如下所列：

- 适用于 QDOT™ Micro 导管：TX *eco* 延长缆线 D135703
- 适用于其他 Biosense Webster 治疗导管：D128603（目录号 CR3434CT）或 D128604（目录号 CR3425CT）

TX *eco* 缆线将来自 Biosense Webster 治疗导管的数据传送到 CARTO™ 3 系统和射频仪。所传送的信息如下：

- 压力信号
- 位置信号
- 来自位于导管尖端的 3 个微电极的 IC 信号（仅适用于带微电极的导管）
- 来自位于导管尖端的 6 个热电偶的温度测量

## 适应症

TX *eco* 缆线将 Biosense Webster 治疗导管连接到 CARTO™ 3 系统（第 6 版及更高版本）的患者接口单元（PIU）。

## 警告

1. 使用本缆线之前，请参阅有关 Biosense Webster 治疗导管的*使用说明*。如果要将此缆线与 QDOT MICRO™ 模块配合使用，在将此缆线与 QDOT MICRO™ 模块配合使用之前，请先参阅 CARTO™ 3 系统的*使用说明*以及 QDOT MICRO™ 模块的*使用说明和版本注释*。
2. 只有阅读并理解本文档内容的工作人员才可以设置和使用此缆线。
3. 此缆线仅能配合 Biosense Webster 治疗导管使用。请勿将此缆线连接到任何其他导管。
4. 此缆线仅适合配合 Biosense Webster 治疗导管、兼容的射频消融仪、CARTO™ 3 系统和 Biosense Webster 缆线使用。详情请咨询您的 Biosense Webster 代表。
5. 手术期间，此缆线与 CARTO™ 3 系统定位台间的距离必须达到至少 1 米（39.4 英寸）。
6. 此缆线在使用前必须连接到 CARTO™ 3 系统的 PIU 预热 5 分钟，确保温度读数准确。预热期之后，温度读数保持稳定。如果在预热期结束前使用缆线，会发生温度漂移。

## 安装和操作缆线

### 连接缆线架

1. 将缆线架夹具部分（零件编号 M652802）置于 CARTO™ 系统车架手柄一侧或者床栏杆上方。然后拧紧缆线架上的旋钮。
2. 将缆线朝下，插入缆线架。

### 连接缆线

1. 将缆线的红色接头连接到位于 CARTO™ 3 系统 PIU 上的 MAP 插口。
2. 将缆线的黄色接头连接到 PIU 上的 QUAD B 或 DECA 插口。

   备注 1：两个接头必须都连接到 PIU。

   备注 2：将接头连接到 QUAD A 会导致不良心电图仪噪音。
3. 如果使用 QDOT™ 微导管，请将导管连接到 TX *eco* 延长缆线的一端。将 TX *eco* 延长缆线的另一端连接到 TX *eco* 缆线末端的大插口。
4. 如果使用另一根 Biosense Webster 治疗导管，请将导管连接到延长缆线的一端。将延长缆线的另一端连接到 TX *eco* 缆线末端的小圆插口。

### 断开缆线

1. 从 CARTO™ 3 系统 PIU 断开红色插头，方法是从滑动释放夹拔出插头。
2. 从 PIU 断开黄色插头，方法是从滑动释放夹拔出插头。

   备注：两个接头必须都从 PIU 断开。不要将一个插头连接，而另一个插头断开。
3. 缆线断开后，等待 10 秒，然后再重新连接到 PIU。

### LED 灯状态

LED 灯将对缆线状态进行指示。缆线正确连接到 CARTO™ 3 系统 PIU 和 Biosense Webster 治疗导管后，缆线进行机内测试（BIT）。

| LED 灯 | 缆线状态 | 注释 |
|---|---|---|
| 绿色：慢速闪烁 | BIT 行中 | --- |
| 绿色：持续点亮 | 准备就绪 | --- |
| 红色：快速闪烁 | 错误，BIT 故障 | 温度未发送到 CARTO™ 3 系统或射频仪。<br>请参阅本文档中的*故障排除*一节。 |

## 护理缆线

### 清洁

缆线不需要消毒或灭菌。不得以蒸煮、高压灭菌器或以其他方式灭菌缆线。

如果缆线上出现灰尘或杂物，按以下方式清洁缆线：

1. 断开缆线。
2. 用布蘸无酒精肥皂水，擦拭缆线，清洁缆线外部。
3. 确保没有皂液进入缆线接头或插口。
4. 确保缆线连接到 CARTO™ 3 系统或导管之前是干燥的。

### 维护

缆线中没有用户可维修部件。如果缆线不能正常工作，请联系客服或您的 Biosense Webster 代表更换缆线。缆线的预期使用寿命为三年。

### 弃置

请将部件回收利用，或根据当地法律法规处置产品及其残留元件或废弃物。

## 技术　据

### 规格

| | |
|---|---|
| **直流输入** | 该缆线从 CARTO™ 3 系统 PIU 接收直流输入。 |
| **重量** | 1 公斤（2.2 磅） |
| **尺寸** | 长 10 英寸 x 宽 1.9 英寸 x 高 3 英寸<br>（254 毫米 x 48 毫米 x 76 毫米） |
| **温度精确度** | ≤ 2°C |

### 操作、储存与运输规格

| | 最低值 | 最高值 |
|---|---|---|
| **操作规格** | | |
| 环境温度 | 10°C | 30°C |
| 相对湿度* | 25% | 75% |
| **储存与运输规格** | | |
| 环境温度 | -30°C | 65°C |
| 相对湿度* | 10% | 95% |

*根据 MIL-STD-1695，搬运或处理电子零件和混合微电子电路区域的相对湿度水平应处于 30% 到 70% 之间的范围。MIL-STD-1695 要求搬运和储存区的相对湿度控制处于前述相同的水平，除非物品被覆盖或受到保护。

### 电磁兼容性信息

TX *eco* 缆线旨在用于 CARTO™ 3 系统*使用说明*中所述的电磁环境中。

## 故障排除

如果 TX *eco* 缆线上的 LED 灯为快速闪烁的红灯，则 BIT 出现故障，引发错误（参见本文档中的 *LED 状态*一节）。按以下步骤解决问题。

1. 从缆线断开导管。
2. 从 CARTO™ 3 系统 PIU 中断开导管。
3. 重新连接到 PIU。
4. 将导管重新连接到缆线。
5. 如果使用 QDOT MICRO™ 模块，按 QDOT MICRO™ 模块的*使用说明和注释模块*行操作。
6. 如果问题仍然未能解决，请联系客服或您的 Biosense Webster 代表。

在系统上施加 15 千伏空气放电或 8 千伏接触放电等情况下，CARTO™ 3 系统将同时显示 3 条错误消息：无法获取地图点（401 错误），患者身体参考已移动（256 错误）和指示患者身体参考更改的弹出窗口。如果发生该种情况，请重新启动 PIU。

## 担　免责及责任限制　明

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## 电子使用说明

您可在 www.e-ifu.com 上找到该文档。

# TX *eco* 電纜

**注意：美國聯邦法律規定本器材僅能由醫生或憑醫囑銷售。**

- 若包裝已拆開或破損，請勿使用。

## 裝置說明

TX *eco* 電纜搭配延長線可用於將 Biosense Webster 治療導管連接到 CARTO™ 3 系統（版本 6 及以上）的患者介面裝置 (PIU)。延長線列出如下：

- 適用於 QDOT™ Micro 導管：TX *eco* 延長線 D135703
- 適用於其他 Biosense Webster 治療導管：D128603（貨號 CR3434CT）或 D128604（貨號 CR3425CT）

TX *eco* 電纜將 Biosense Webster 治療導管的資料傳輸至 CARTO™ 3 系統和射頻產生器。傳達的資訊列出如下。

- 力度訊號
- 位置訊號
- 導管尖端 3 個微電極傳來的 IC 訊號（僅適用於帶微電極的導管）
- 導管尖端 6 個熱電偶傳來的溫度測量值

## 適應症

TX *eco* 電纜可用於將 Biosense Webster 治療導管連接到 CARTO™ 3 系統（版本 6 及以上）的患者介面裝置 (PIU)。

## 警告

1. 使用本電纜前，務必閱讀 Biosense Webster 治療導管的*使用說明*。若將本電纜與 QDOT MICRO™ 模組聯用，則在將本電纜與 QDOT MICRO™ 模組聯用前，先參閱 CARTO™ 3 系統的*使用說明*以及 QDOT MICRO™ 模組的*使用說明與發行備註*。
2. 閱讀並瞭解此使用說明內容的人員才可設定與使用本電纜。
3. 經驗證，本電纜僅可與 Biosense Webster 治療導管聯用。切勿將此電纜連接到任何其他導管。
4. 本電纜旨在僅與 Biosense Webster 治療導管、相容射頻產生器、CARTO™ 3 系統、Biosense Webster 纜線搭配使用。請諮詢您的 Biosense Webster 代表瞭解詳細資訊。
5. 手術期間，本電纜必須與 CARTO™ 3 系統的定位臺間隔至少 1 公尺（39.4 英吋）。
6. 使用前，本電纜必須連接到 CARTO™ 3 系統患者介面裝置預熱 5 分鐘，以確保溫度讀數準確。預熱完成後，溫度讀數將保持穩定。若在預熱期間使用電纜，可能會發生溫度偏移。

## 電纜安裝與操作

### 連接電纜架

1. 將電纜架（部件編號 M652802）的夾持部份置於 CARTO™ 系統推車手柄的側面或床欄桿上方。隨後擰緊電纜架上的旋鈕。
2. 將電纜插入電纜架，使電纜朝下。

### 連接電纜

1. 將電纜的紅色接頭插入 CARTO™ 3 系統患者介面裝置上的 MAP 接口。
2. 將電纜的黃色接頭插入患者介面裝置上的 QUAD B 或 DECA 接口。

   附註 1：兩個接頭都須插入患者介面裝置。

   附註 2：將接頭插入 QUAD A 可能導致心電圖 (ECG) 異常噪音。
3. 若使用的是 QDOT™ Micro 導管，將導管連接到 TX *eco* 延長線電纜的一端。將 TX *eco* 延長線電纜的另一端插入 TX *eco* 電纜末端的大接口。
4. 若使用的是其他 Biosense Webster 治療導管，將導管連接到延長線電纜的一端。將延長線電纜的另一端插入 TX *eco* 電纜末端的圓形小接口。

### 斷開電纜連接

1. 透過將接頭從滑動釋放接口拔出，斷開紅色接頭與 CARTO™ 3 系統患者介面裝置的連接。
2. 透過將接頭從滑動釋放接口拔出，斷開黃色接頭與患者介面裝置的連接。

   附註：兩個接頭都必須從患者介面裝置斷開連接。切勿僅斷開其中一個電纜的連接。
3. 拔出電纜後，如需重新將電纜連接到病患介面裝置，請等待 10 秒再行操作。

### LED 燈狀態

LED 燈可指示電纜狀態。電纜正確連接到 CARTO™ 3 系統病患介面裝置和 Biosense Webster 治療導管後，會自動執行內建測試 (BIT)。

| LED 燈 | 電纜狀態 | 備註 |
|---|---|---|
| 綠色：緩慢閃爍 | 內建測試運行中 | --- |
| 綠色：長亮 | 準備就緒 | --- |
| 紅色：快速閃爍 | 發生錯誤，內建測試失敗 | 溫度未能傳送至 CARTO™ 3 系統或射頻產生器。<br>請參閱本文件*疑難排解*一節。 |

### 電纜維護

#### 清潔

電纜無需滅菌或消毒。請勿使用蒸汽、高壓滅菌器等方式對電纜進行滅菌。

若電纜上有灰塵或碎屑，請按以下操作清潔電纜：

1. 斷開電纜連接。
2. 用不含酒精的洗手皂加水兌成皂液，浸濕抹布，擦拭電纜外部進行清潔。
3. 確保皂液未流入電纜接頭或接口。
4. 確保在連接到 CARTO™ 3 系統或導管前，電纜已充分乾燥。

#### 維護

電纜中的任何部件皆不可由使用者自行維修。若電纜出現故障，請洽詢客戶支援或您的 Biosense Webster 代表以進行更換。電纜預期使用壽命為三年。

#### 棄置

請按照當地法律和法規回收組件或棄置本產品及其殘留組件或廢棄物。

## 技術資料

### 產品規格

| | |
|---|---|
| **直流輸** | 電纜從 CARTO™ 3 系統患者介面裝置接收電源輸入。 |
| **重量** | 1 公斤（2.2 磅） |
| **尺** | 長 10 英吋 x 寬 1.9 英吋 x 高 3 英吋<br>（254 公釐 x 48 公釐 x 76 公釐） |
| **溫度準確度** | ≤ 2°C |

### 作業、儲存與運輸規格

| | 最低值 | 最高值 |
|---|---|---|
| **作業規格** | | |
| 環境溫度 | 10°C | 30°C |
| 相對濕度* | 25% | 75% |
| **儲存與運輸規格說明** | | |
| 環境溫度 | -30°C | 65°C |
| 相對濕度* | 10% | 95% |

* 根據 MIL-STD-1695，處理或操作電子部件和混合微電路時，環境相對濕度水平應處於 30% 到 70% 的範圍內。MIL-STD-1695 要求操作區域和儲存區域的相對濕度控制水平相同，裝置被覆蓋或受到保護的情況除外。

### 電磁　容性資訊

根據 CARTO™ 3 系統的*使用說明*，TX *eco* 電纜預期可在電磁環境中使用。

## 疑難排解

若 TX *eco* 電纜上的 LED 燈為紅色且快速閃爍，則表明內建測試失敗，存在錯誤（見本文件 ***LED** 燈狀態*一節）。請按以下步驟解決問題。

1. 斷開導管與電纜的連接。
2. 從 CARTO™ 3 系統患者介面裝置拔出電纜。
3. 重新將電纜連接到患者介面裝置。
4. 重新將導管連接到電纜。
5. 若使用 QDOT MICRO™ 模組，請按照 QDOT MICRO™ 模組*使用說明與發行備註*中的使用方法進行操作。
6. 若故障仍然存在， 請洽詢客戶支援或您的 Biosense Webster 代表。

某些情況下，在系統上施加 15 kV 的空氣放電或 8 kV 的接觸放電時，CARTO™ 3 系統會同時顯示 3 條錯誤訊息：無法獲取繪圖點（錯誤 401），患者身體參考物已移動（錯誤 256）和指示患者身體參考物變化的快顯視窗。如果出現此等情況，則重新啟動患者介面裝置。

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## 電子使用說明

可至 www.e-ifu.com 取得本文件。

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EML140102IFU01B

Rev: 2022-10