TactiFlex™ Ablation Catheter, Sensor Enabled™

REF

A-TFSE-D, A-TFSE-F, A-TFSE-J, A-TFSE-DD, A-TFSE-FF, A-TFSE-JJ, A-TFSE-DF, A-TFSE-FJ

Instructions for Use

Abbott

EN: English

TactiFlex™ Ablation Catheter, Sensor Enabled™

Instructions for Use

Description

The TactiFlex™ Ablation Catheter, Sensor Enabled™ is designed to facilitate electrophysiological mapping of the heart chambers and to transmit radiofrequency (RF) current to the catheter flexible tip electrode for intracardiac ablation. For ablation, the catheter is used in conjunction with an RF generator, an irrigation pump, and a dispersive pad (indifferent patch electrode). The TactiFlex™ Ablation Catheter, Sensor Enabled™ is compatible with introducers or sheaths with a minimum inner diameter of 8.5 F.

The TactiFlex™ Ablation Catheter, Sensor Enabled™ features a tri-axial optical force sensor embedded in the distal section of the catheter that transmits contact force information to the TactiSys™ Quartz Equipment.

The TactiFlex™ Ablation Catheter, Sensor Enabled™ is a sterile, single use catheter with a 7.5 F shaft and an 8 F distal section. It is constructed of thermoplastic elastomer material and noble metal electrodes. The catheter has a force and magnetic sensor. It has a fluid lumen connected to a flexible tip electrode for saline irrigation during the ablation procedure. For both bi-directional and uni-directional catheters, the tip curvature is manipulated by the control mechanism located on the handle at the catheter's proximal end. To adjust the curve of the distal tip on the uni-directional catheter, push or pull the thumb control located on the handle. To adjust the curve of the distal tip on the bi-directional catheter, use the actuator to deflect the catheter in either direction. The catheters are available in eight distal curve configurations listed in the table below. The curve is identified on the catheter label. The device and packaging are not made with natural rubber latex.

Table 1. Catheter Curve Configurations

Catheter Type	Curve	Model Number
Uni-directional	D	A-TFSE-D
	F	A-TFSE-F
	J	A-TFSE-J
Bi-directional	D-D	A-TFSE-DD
	F-F	A-TFSE-FF
	J-J	A-TFSE-JJ
	D-F	A-TFSE-DF
	F-J	A-TFSE-FJ

The catheter connects to the TactiSys™ Quartz Equipment (PN-004 400) and, directly or indirectly, to a compatible RF cardiac ablation generator, irrigation pump, and 3D mapping/contact force display system. Compatible systems components are listed below. For information regarding their use, refer to the appropriate instructions for use.

Table 2. Compatible Systems

System Device	Connect via (Model Number)	System Software
Ampere™ RF Ablation Generator	TactiFlex™ RF cable for use with TactiSys™ Quartz and Ampere™ Generator (TSQ-RF-TFSE-CBL)	v1.0.6 or later
Cool Point™ Irrigation Pump	Cool Point™ Tubing Set (85785)	v24 or later
EnSite™ X EP System *	Ethernet cable supplied with TactiSys™ Quartz equipment 10-pin connector from catheter integrated cable	v1.1 or later
EnSite™ X Contact Force Module		
TactiFlex SE Module		v1.0 or later

* Optional: Magnetic Extension 10 Pin Ensite™ X Cable (A-ENS-MAGEXT-CBL)

Indications for Use

The TactiFlex™ Ablation Catheter, Sensor Enabled™ is indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation and concomitant atrial flutter, when used in conjunction with a compatible RF generator and three-dimensional mapping system.

Contraindications

The catheter is contraindicated for:

- Patients who have had a ventriculotomy or atriotomy within the preceding four weeks.
- Patients with prosthetic valves as the catheter may damage the prosthesis.
- Patients with an active systemic infection as this may increase the risk for cardiac infection.
- Use in coronary vasculature due to risk of damage to the coronary arteries.
- Patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolus.
- The transseptal approach in a patient with an interatrial baffle or patch because the opening could persist and produce an iatrogenic atrial shunt.
- The retrograde trans-aortic approach in patients who have had aortic valve replacement.
- Patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation.

Warnings

- The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data.
- Application of RF energy outside of the power and duration recommendations may increase the likelihood of steam pop occurrence.
- Contact force in excess of 20 g may not significantly change the characteristics of lesion formation.

- Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Permanent pacing may be required in patients who experience inadvertent complete AV block as a result of RF ablation.
- Implantable pacemakers and implantable cardioverter/defibrillator (ICDs) may be adversely affected by RF current. It is important to:
  - Have temporary external sources of pacing and defibrillation available during ablation.
  - Temporarily reprogram the pacing system to minimum output to minimize 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.
  - Perform complete implantable device analysis on all patients after ablation.
- The combination of intracoronary placement of the ablation catheter and RF energy application has been associated with myocardial infarction and death.
- Minimize X-ray exposure during the procedure. Catheter ablation procedures 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 the fluoroscopic imaging. Catheter ablation 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 and prepubescent children.
- Inspect tubing, connections, and saline irrigation for air bubbles prior to and throughout its use in the procedure. Air or bubbles in the saline irrigation may cause emboli, potential injury, or fatality.
- Do not prime the tubing set while the catheter is in the patient. Remove catheter from patient and use prime to purge air or bubbles from the system.
- Do not immerse the proximal handle or cable connectors in fluids; electrical performance could be affected.
- When using steerable sheaths, make sure the sheath tip is straight during introduction or withdrawal of the catheter.
- Increased contact force may increase the risk for perforation during manipulation of the catheter.
- Contact force accuracy above 50 g has not been established.
- The catheter temperature and impedance display of the cardiac ablation generator should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted that does not exceed the preset limit, or a steam pop is observed, power delivery should be manually discontinued. Clinically assess the situation. If necessary, the catheter should be removed from the patient and the distal tip of the catheter cleaned to eliminate any coagulum.
- Caution should be taken when placing lesions in the proximity of the specialized conduction system.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- When using an electrophysiology (EP) recording system, the equipment must be front-end isolated, or have an isolated patient cable.
- When ablating near the phrenic nerve, take precautions to avoid injuring the phrenic nerve, including appropriately reducing RF power and pacing to identify the proximity of the nerve.
- Cases of delayed onset of atrio-esophageal fistula (AEF) have been reported in association with radiofrequency catheter ablation procedures. While rare, AEF is associated with significant morbidity and mortality.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of RF catheter ablation in a fully equipped EP laboratory.
- The long-term risks of protracted fluoroscopy and creation of RF induced lesions have not been established, particularly with respect to lesions placed in proximity to the specialized conduction system. Careful consideration must therefore be given for the use of the device in pregnant women and prepubescent children. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
- The catheter is intended for single use only. Do not reprocess or reuse. Reuse can cause device failure, patient injury, and/or the communication of infectious disease(s) from one patient to another.
- The catheter used in conjunction with a RF generator is capable of delivering significant RF power. Patient or operator injury can result from improper handling of the catheter and indifferent electrode, particularly when operating the device. During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces. Position RF patient cables to avoid contact with the patient or other cables.
- 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.
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- To avoid thromboemboli, intravenous heparin should be used when entering the left heart during ablation. Consult the HRS consensus guidelines for anticoagulation strategies pre-, during, and post-catheter ablation. [1]
- Always maintain a constant saline irrigation flow to prevent coagulation within the lumen of the catheter.
- 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 instructions on how to zero the contact force reading.
- To ensure correct use of the intracardiac electrogram signals, the distal portion of the catheter should have the tip and all electrodes outside of the introducer sheath.
- To ensure correct use of the force sensor, the distal portion of the catheter should have the tip and one additional electrode outside of the introducer sheath.
- When using the catheter with conventional EP lab system (using fluoroscopy to determine catheter tip location) or with a 3D navigational system, careful catheter manipulation must be performed, especially when used in combination with a long sheath, in order to avoid cardiac damage, perforation, or tamponade. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. If force sensing functionality is active, evaluate applied force to avoid applying excessive force.

Precautions

- When using the catheter in combination with a sheath and to prevent occlusion of the irrigation line, avoid applying simultaneous high torque and tensile stress (pulling) to the catheter while the catheter tip is engaged in the sheath in a curved position.
- Release the steering (make the catheter straight) when pulling back the catheter into the sheath.
- The steerability feature of the catheter is designed to operate in a single plane of motion. Moving the deflectable section in other planes (e.g. perpendicular to normal steering plane, etc.) may damage the steering mechanism and impair the operator's ability to position the catheter tip as desired. Do not use the catheter with deflectable introducer sheaths that operate in multiple planes of motion. Do not use the catheter with deflectable sheaths that may constrain catheter tip deflection through the use of manually operated hemostatic valves.
- Always straighten the catheter tip before insertion or withdrawal.
- Do not scrub or twist the tip electrode. Damage to the tip electrode or the tip electrode bond may occur.
- To avoid fluid volume overload, monitor the patient's fluid balance prior to and during the procedure.

[1] Calkins, H., Hindricks, G., Cappato, R., Kim, Y.-H., Saad, E. B., Aguinaga, L., Akar, J. G., et al. (2017). 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Heart Rhythm, 14(10), e275–e444. Elsevier BV. Retrieved from http://dx.doi.org/10.1016/j.hrthm.2017.05.012

- Apparent low power output, high impedance reading, or failure of the RF equipment to function correctly at normal settings may indicate faulty application of the indifferent electrode(s) or failure of an electrical lead. Check for defects or misapplication of the indifferent electrode or other electrical leads before increasing power.
- When ablating near adjacent anatomical structures, take precautions to minimize collateral damage to the adjacent structures.
- The sterile packaging and catheter should be inspected prior to use. Do not use if the packaging or catheter appears damaged.
- Do not expose catheter to organic solvents such as alcohol.
- Electromagnetic interference (EMI) produced by the catheter when used in conjunction with a RF generator during normal operation may adversely affect the performance of other equipment.
- Electrodes and probes for monitoring and stimulating devices can provide paths for high frequency current. The risk of burns can be reduced by placing the electrodes and probes as far away as possible from the ablation site and the indifferent electrode. Protective impedances may reduce the risk of burns, and permit continuous monitoring of the electrocardiogram during energy delivery. Monitoring systems incorporating high frequency current limiting devices are recommended. Needle monitoring electrodes are not recommended.
- If the generator does not display temperature, verify that the appropriate cable is plugged into the generator. If temperature still is not displayed, there may be a malfunction in the temperature sensing system which must be corrected prior to applying RF power.
- Before use, check that irrigation is fully functional by infusing saline through the catheter.
- Store in a cool, dark place.
- Do not attempt to operate the device prior to completely reading and understanding the applicable instructions for use.
- Carefully align the optical connector with the TactiSys™ Quartz Equipment optical socket while firmly pushing in order to ensure connection.
- Do not use contrast fluid in catheter.
- If irrigation flow is interrupted, immediately inspect and re flush the catheter outside of the patient. Re-establish irrigation flow prior to placing catheter in the body.
- Do not use if catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve and/or if any of the irrigation ports are blocked.
- If the Cool Point™ Irrigation Pump alarm sounds, RF energy will be terminated. Communication between the Cool Point™ Irrigation Pump and the Ampere™ RF Generator should be evaluated. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. Remove the catheter from the patient and inspect the catheter and the electrodes. If necessary, clean the electrodes with a sterile saline saturated gauze pad. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion.
- Do not attempt ablation without using the Cool Point™ Irrigation Pump.
- Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Be careful when ablating near electrically vulnerable, thin walled, or other arterial structures.
- Position connecting cables to avoid contact with the patient and other electrical leads.
- After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.
- Excessive bending or kinking of the catheter may cause damage to the catheter. Manual pre-bending of the distal curve can impact catheter performance and irrigation flow, and may cause patient injury.
- Do not use the catheter if not working properly. Check functionality of irrigation and steering mechanism carefully.

Adverse Events

The following adverse events have been documented for catheter ablation procedures:

- Abnormal vision
- Anesthesia reaction
- Angina / chest pain / discomfort
- Aorto-right atrial fistula
- Arrhythmia, including exacerbation of pre-existing atrial fibrillation
- Arteriovenous fistula
- Bleeding, including major bleeding requiring surgery or transfusion / hematomas / anemia
- Cardiac tamponade
- Cardiovascular injury, including atrial trauma and cardiac perforation / Laceration / Dissection, vessel, coronary artery / pulmonary vein
- Coronary artery spasm
- Cytotoxicity / systemic toxicity / sensitization / endotoxin / pyrogen
- Death
- Dislodgement of implantable cardioverter defibrillator or pacing leads / Component damage to ICD or implantable pacemaker
- Effusion, pericardial
- Effusion, pleural
- Embolism, air / cardiac / pulmonary / pulmonary vein
- Endocarditis
- Exacerbation of chronic obstructive pulmonary disease (COPD)
- Fever
- Heart block / Unintended ablation
- Heart failure
- Hypotension
- Immunological reaction, including anaphylaxis
- Infection
- Left atrial esophageal fistula / Organ injury
- Myocardial infarction / Elevated cardiac enzymes
- Pain, neck / back/groin
- Palpitations
- Pericarditis
- Phrenic nerve injury / diaphragmatic paralysis
- Pneumonia
- Pneumothorax / hemothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary hypertension
- Radiation injury
- Respiratory failure/distress / depression/hypoxia
- Sepsis / Shock
- Severe pulmonary vein (PV) stenosis (>70%), or complete occlusion of a PV / Cough
- Skin burns / Electrical shock / injury
- Stiff Left Atrial Syndrome
- Stroke / cerebrovascular accident / Thromboembolism / Embolism, material/ component / Coagulation / Disseminated intravascular coagulation / Tissue charring / Seizure
- Syncope / vasovagal reaction / dizziness
- Thrombus, including coronary artery / vessel occlusion
- Transient ischemic attack (TIA)
- Vagal nerve injury / gastroparesis
- Valvular damage or insufficiency
- Vessel wall damage
- Volume overload

Clinical Study Information

Study Objectives

The objective of the TactiFlex™ Paroxysmal (PAF) IDE clinical trial was to demonstrate that ablation with the TactiFlex™ Ablation Catheter, Sensor-Enabled™ (TactiFlex™ SE), is safe and effective for the treatment of drug refractory, symptomatic paroxysmal atrial fibrillation (AF) when following standard electrophysiology mapping and radiofrequency (RF) ablation procedures.

The TactiFlex™ PAF IDE clinical trial had two additional objectives:

1. High Standard Power - To provide supporting data for the safety and effectiveness of using TactiFlex™ SE at 40-50 Watts in the left atrium as part of an AF ablation procedure.
2. Typical Atrial Flutter - To provide supporting data for the safety and effectiveness of using TactiFlex™ SE to treat cavo-tricuspid isthmus (CTI)-dependent (or “typical”) atrial flutter (AFL) through the ablation of the CTI in the right atrium. This data may be used to support an expanded indication for the treatment of CTI-dependent AFL.

Study Design

This was a prospective, non-randomized, multi-center pivotal clinical trial to evaluate the safety and effectiveness of ablation with the TactiFlex™ SE catheter for the treatment of PAF compared to pre-determined performance goals. The clinical study enrolled a total of 355 subjects at 370 investigational sites worldwide. Fifty (50) subjects were enrolled in the High Standard Power (HSP) Substudy, and 305 subjects were enrolled in the Main Study.

Study Population

This clinical investigation enrolled male and female subjects who had drug refractory, symptomatic, paroxysmal AF.

Key Study Endpoints

There were two primary and three secondary endpoints for this study.

Primary Safety Endpoint

The primary safety endpoint was the rate of device and/or procedure-related serious adverse events with onset within 7-days of any ablation procedure that used the TactiFlex™ SE catheter (initial or repeat procedure performed 31-80 days of initial procedure) that are defined below:

- Atrio-esophageal fistula
- Cardiac tamponade/perforation
- Death
- Heart block
- Myocardial infarction
- Pericarditis
- Phrenic nerve injury resulting in diaphragmatic paralysis
- Pulmonary edema
- Pulmonary vein stenosis
- Stroke/cerebrovascular accident
- Thromboembolism
- Transient ischemic attack
- Vagal nerve injury/gastroparesis
- Vascular access complications (including major bleeding events)

Atrioesophageal fistula, cardiac tamponade/perforation and pulmonary vein stenosis were evaluated through 12-months. Pericarditis was considered a major complication following ablation if it resulted in an effusion that led to hemodynamic compromise or required pericardiocentesis, prolonged hospitalization by more than 48 hours, required hospitalization, or persisted for more than 30 days following the ablation procedure. Bleeding was considered a major complication of AF ablation if it required and/or was treated with transfusion or results in a 20% or greater fall in hematocrit.

Primary Effectiveness Endpoint

The primary effectiveness endpoint was freedom from documented (symptomatic or asymptomatic) AF/AFL/Atrial Tachycardia (AT) episodes of >30 seconds duration that was documented by an ECG (12-lead ECG or TTM) or Holter monitor after the initial catheter ablation procedure through 12-months of follow-up (9 months after a 90-day blanking period). One repeat procedure was allowed for ablation of AF/AFL/AT recurrence during the blanking period (≤80 days post-initial procedure) without being considered a treatment failure.

AF/AFL/AT recurrence was only assessed by 12-lead ECG, TTM, and Holter monitoring devices for assessment of this primary endpoint so that all subjects were monitored equally with devices of the same sensitivity and specificity. Collected ECG, TTM, and Holter data from sites was evaluated by a core laboratory to ensure independent and unbiased assessment of AF/AFL/AT recurrence for endpoint analysis.

The following events were considered a failure for the primary effectiveness endpoint:

- If the subject fails to achieve acute procedural success, defined as confirmation of entrance block in all pulmonary veins after a minimum waiting period of 20-minutes, during last ablation procedure performed with the TactiFlex™ SE catheter, or
- If documented AF/AFL/AT recurrence (>30 second episode) occurs at any time after the blanking period (>90 days after the initial procedure), or
- If the subject requires a repeat procedure for the treatment of AF >80 days after the initial procedure, the subject will be considered an effectiveness endpoint failure regardless of documentation of a >30 second AF/AFL/AT episode, or
- If the subject requires a second repeat AF ablation procedure ≤80 days after the initial procedure, or
- Any use of a new class I or III AAD for AF after the blanking period, or
- Any use of a class I or III ADD for AF at a dose higher than that previously failed by the patient, or
- If the subject requires a cardioversion (electrical or pharmacological) for the treatment of AF after the blanking period, or

- If the subject has a continuous atrial arrhythmia throughout a 12-lead ECG recording after the blanking period indicating AF/AFL/AT recurrence, this will be considered sufficient documentation of recurrence unless there is evidence that the recorded arrhythmia is short-lived and less than 30 seconds as determined by the investigator, or
- Any ablation in the left atrium using an ablation catheter other than TactiFlex™ SE.

Cavotricuspid isthmus (CTI)-dependent AFL that occurs alone either during or after the blanking period will be considered an exception to being considered a recurrence. Occurrence of CTI-dependent AFL confirmed by entrainment maneuvers that occurs at any time during the follow-up period and is ablated, will not be considered a primary effectiveness endpoint failure.

Secondary Endpoint

Three secondary endpoints were evaluated in this study (Main Study):

1. Symptomatic Secondary Effectiveness Endpoint - The Symptomatic Secondary Effectiveness Endpoint has the same definition as the Primary Effectiveness Endpoint, except that any episodes of documented recurrence without documented evidence of symptoms after the 90-day blanking period was not counted as a therapy failure.
2. Single-Procedure Secondary Effectiveness Endpoint - The Single-Procedure Secondary Effectiveness Endpoint has the same definition as the Primary Effectiveness Endpoint, except that any repeat ablation in the left atrium was counted as a failure.
3. AAD-Free Secondary Effectiveness Endpoint - The AAD-Free Secondary Effectiveness Endpoint has the same definition as the Primary Effectiveness Endpoint, except that any use of Class I or III AADs after the 90-day blanking period was counted as a therapy failure.

Total number of Enrolled Study Sites and Subjects, Follow-up Rate

The study enrolled a total of 355 subjects, 305 in the Main Study and 50 in the HSP Substudy, at 37 sites within United States, Canada, Australia, Italy, Austria, Germany, Canada, Czech Republic, Hong Kong, and Taiwan.

Study Visits and Length of Follow-Up

The scheduled study visits included Baseline, Procedure, Pre-Discharge, 7-day, 5-week, 3-month, 6-month, and 12-month which was the finial visit of the study.

Subject Analysis Populations

Per Treatment Evaluable (PTE): All subjects enrolled within the Main Study or HSP Substudy who had the investigational catheter inserted into their vasculature for the ablation procedure.

Per Protocol (PP): Main Study cohort subjects that included Main Study PTE subjects without protocol deviations for either eligibility or using a non-investigational catheter for any ablation procedure to treat AF. Subjects ablated at a power setting >50W was also excluded from this population.

As Treated (AT): PTE subjects from both Main Study and HSP Substudy cohorts who were enrolled, had the investigational catheter inserted into their vasculature for the ablation procedure, and have Ampere and AutoMark data available.

Primary Effectiveness Analysis Population (EFF): Subjects from the Main Study or HSP Substudy from the PTE population who had RF energy delivered.

Primary Safety Analysis Population (SAF): Subjects from the Main Study or HSP Substudy from the PTE population who completed the 7-day follow-up visit or crossed the end of the 7-day visit window, but without a primary safety event.

Demographics

The table below summaries the study demographic information for the Per Treatment Evaluable (PTE) analysis populations.

Table 3. Demographics and Baselines Characteristics (PTE populations)

Characteristics	Main Study Cohort (N=284)	HSP Substudy Cohort (N=50)	All Subjects (N=334)
Age (yrs)			
Mean ± SD (n)	62.9 ± 11.2 (284)	65.1 ± 9.3 (50)	63.2 ± 10.9 (334)
Median (Q1, Q3)	65.0 (56.0, 71.0)	67.0 (61.0, 70.0)	65.0 (56.0, 71.0)
Range (min, max)	(23, 87)	(41, 81)	(23, 87)
Gender			
Male	63.4% (180/284)	68.0% (34/50)	64.1% (214/334)
Female	36.6% (104/284)	32.0% (16/50)	35.9% (120/334)
Ethnicity			
Hispanic or Latino	1.8% (5/284)	4.0% (2/50)	2.1% (7/334)
Not Hispanic or Latino	93.0% (264/284)	90.0% (45/50)	92.5% (309/334)
Declined/Unknown	5.3% (15/284)	6.0% (3/50)	5.4% (18/334)
Race			
Declined or Unable to Disclose	2.8% (8/284)	4.0% (2/50)	3.0% (10/334)
American Indian or Alaskan Native	0.0% (0/284)	0.0% (0/50)	0.0% (0/334)
Asian	3.5% (10/284)	4.0% (2/50)	3.6% (12/334)
Chinese	60.0% (6/10)	0.0% (0/2)	50.0% (6/12)
Korean	0.0% (0/10)	0.0% (0/2)	0.0% (0/12)
Japanese	10.0% (1/10)	0.0% (0/2)	8.3% (1/12)

Table 3. Demographics and Baselines Characteristics (PTE populations)

Characteristics	Main Study Cohort (N=284)	HSP Substudy Cohort (N=50)	All Subjects (N=334)
Other	30.0% (3/10)	100.0% (2/2)	41.7% (5/12)
Black or African American	1.1% (3/284)	2.0% (1/50)	1.2% (4/334)
Native Hawaiian or Pacific Island	0.0% (0/284)	0.0% (0/50)	0.0% (0/334)
White or Caucasian	92.3% (262/284)	88.0% (44/50)	91.6% (306/334)
Other	0.4% (1/284)	2.0% (1/50)	0.6% (2/334)
Height (cm)			
Mean ± SD (n)	175.20 ± 10.33 (284)	175.49 ± 9.60 (50)	175.25 ± 10.21 (334)
Median (Q1, Q3)	176.75 (167.60, 182.90)	177.80 (167.60, 182.90)	177.40 (167.60, 182.90)
Range (min, max)	(149.9, 203.0)	(154.9, 193.0)	(149.9, 203.0)
Weight			
Mean ± SD (n)	90.14 ± 17.22 (284)	88.12 ± 18.37 (50)	89.84 ± 17.39 (334)
Median (Q1, Q3)	90.45 (78.45, 101.00)	90.30 (73.50, 103.40)	90.35 (77.10, 101.60)
Range (min, max)	(49.9, 134.0)	(54.4, 131.5)	(49.9, 134.0)
BMI			
Mean ± SD (n)	29.37 ± 5.03 (284)	28.50 ± 4.65 (50)	29.24 ± 4.98 (334)
Median (Q1, Q3)	28.40 (25.60, 33.00)	28.35 (25.90, 30.40)	28.40 (25.70, 32.80)
Range (min, max)	(15.8, 40.0)	(18.7, 39.2)	(15.8, 40.0)
CHA2DS2Vasc Score			
Mean ± SD (n)	2.0 ± 1.4 (284)	2.2 ± 1.2 (49)	2.0 ± 1.4 (333)
Median (Q1, Q3)	2.0 (1.0, 3.0)	2.0 (2.0, 3.0)	2.0 (1.0, 3.0)
Range (min, max)	(0, 7)	(0, 6)	(0, 7)
NYHA Classification			
No HF	71.5% (203/284)	88.0% (44/50)	74.0% (247/334)
I	19.0% (54/284)	2.0% (1/50)	16.5% (55/334)
II	9.5% (27/284)	10.0% (5/50)	9.6% (32/334)
III or IV	0.0% (0/284)	0.0% (0/50)	0.0% (0/334)
Echo/CT- LVEF (%)			
Mean ± SD (n)	58.02 ± 6.26 (284)	56.43 ± 5.89 (50)	57.79 ± 6.22 (334)
Median (Q1, Q3)	60.00 (55.00, 60.00)	55.00 (55.00, 60.00)	60.00 (55.00, 60.00)
Range (min, max)	(35.0, 73.0)	(35.0, 75.0)	(35.0, 75.0)
Echo/CT- LA Diameter (mm)			
Mean ± SD (n)	39.4 ± 5.9 (284)	39.0 ± 5.6 (49)	39.0 ± 5.9 (333)
Median (Q1, Q3)	40.0 (36.0, 43.0)	40.0 (36.0, 43.0)	40.0 (36.0, 43.0)
Range (min, max)	(20, 50)	(29, 50)	(20, 50)

Table 4. Arrhythmic, Surgical, and Medical History (PTE populations)

Characteristic	Main Study Cohort (N=284)	HSP Substudy Cohort (N=50)	All Subjects (N=334)
Arrhythmia History			
Paroxysmal AF	100.0% (284/284)	100.0% (50/50)	100.0% (334/334)
Atrial flutter			
No AFL	77.1% (219/284)	66.0% (33/50)	75.4% (252/334)
Typical AFL	11.3% (32/284)	30.0% (15/50)	14.1% (47/334)
Atypical AFL	1.4% (4/284)	0.0% (0/50)	1.2% (4/334)
Unknown AFL	10.2% (29/284)	4.0% (2/50)	9.3% (31/334)
Atrial Tachycardia	2.1% (6/284)	6.0% (3/50)	2.7% (9/334)
Ventricular Tachycardia	5.3% (15/284)	18.0% (9/50)	7.2% (24/334)
Heart Block 1st Degree	2.5% (7/284)	6.0% (3/50)	3.0% (10/334)
Heart Block 2nd Degree	0.4% (1/284)	0.0% (0/50)	0.3% (1/334)
Heart Block 3rd Degree	0.4% (1/284)	0.0% (0/50)	0.3% (1/334)

AV Nodal Dysfunction	0.7% (2/284)	2.0% (1/50)	0.9% (3/334)
Bradycardia	4.6% (13/284)	2.0% (1/50)	4.2% (14/334)
SVT	0.4% (1/284)	0.0% (0/50)	0.3% (1/334)
Surgical History			
Left atrial or catheter ablation [2]	0.4% (1/284)	0.0% (0/50)	0.3% (1/334)
Procedure incision with resulting scar	0.0% (0/284)	0.0% (0/50)	0.0% (0/334)
Valve replacement or repair	0.0% (0/284)	0.0% (0/50)	0.0% (0/334)
Percutaneous coronary intervention	7.4% (21/284)	10.0% (5/50)	7.8% (26/334)
Arrhythmia due to reversible causes	0.0% (0/284)	0.0% (0/50)	0.0% (0/334)
Implanted with an ICD	1.1% (3/284)	0.0% (0/50)	0.9% (3/334)
Implanted with a pacemaker	5.6% (16/284)	6.0% (3/50)	5.7% (19/334)
Disease History			
Bleeding or clotting disorder	0.0% (0/284)	0.0% (0/50)	0.0% (0/334)
Coronary Artery disease	16.5% (47/284)	18.0% (9/50)	16.8% (56/334)
CABG surgery	1.4% (4/284)	0.0% (0/50)	1.2% (4/334)
Acute coronary syndrome	1.1% (3/284)	2.0% (1/50)	1.2% (4/334)
Diabetes	12.7% (36/284)	10.0% (5/50)	12.3% (41/334)
Heart Failure	22.5% (64/284)	14.0% (7/50)	21.3% (71/334)
Hypertension	58.8% (167/284)	60.0% (30/50)	59.0% (197/334)
Myocardial infarction (MI)	4.2% (12/284)	6.0% (3/50)	4.5% (15/334)
Obstructive Sleep Apnea	18.3% (52/284)	20.0% (10/50)	18.6% (62/334)
Non-Severe Pulmonary disease	4.9% (14/284)	6.0% (3/50)	5.1% (17/334)
Stroke	3.9% (11/284)	2.0% (1/50)	3.6% (12/334)
Transient ischemic attack (TIA)	1.1% (3/284)	4.0% (2/50)	1.5% (5/334)
Structural Heart disease	7.0% (20/284)	2.0% (1/50)	6.3% (21/334)
Thromboembolism	1.8% (5/284)	2.0% (1/50)	1.8% (6/334)
Thyroid disease	5.6% (16/284)	16.0% (8/50)	7.2% (24/334)
Renal failure	1.8% (5/284)	0.0% (0/50)	1.5% (5/334)

Summary of Main Study Results

Primary Effectiveness Results

Table 5. Primary Effectiveness Endpoint (Main Study, EFF population)

Endpoint	Rate	97.5% KM lower bound	Performance Goal
Primary Effectiveness Endpoint	72.9%	67.2%	>50.0%

Primary Safety Results

Table 6. Primary Safety Endpoint (Main Study, SAF population)

Endpoint	Proportion of Subjects	97.5% Exact Binomial Upper Bound	Performance Goal
Primary Safety Endpoint	4.3% (12/280)	7.4%	< 12.9%

Table 7. Primary Safety Endpoint Events (Main Study)

Endpoint Criteria	Number of Events	Proportion of Subjects (N=280)
Vascular access complications (including major bleeding events)	5	1.8%
Cardiac tamponade/perforation	2	0.7%
Pericarditis	2	0.7%
Pulmonary edema	2	0.7%
Transient ischemic attack	1	0.4%
Total	**12**	**4.3%**

[2] Subject 1561 had a prior surgery in the left atrium. This was an inclusion/exclusion criteria protocol deviation.

Secondary Endpoint Results

Given that both the primary effectiveness and primary safety endpoints were met, the powered secondary endpoints were evaluated. Analysis population for secondary endpoints were based off of the EFF population with additional exclusions related to specific failure definitions per endpoint.

Table 8. Symptomatic Effectiveness (Main Study)

Endpoint	Rate	97.5% KM lower bound	Performance Goal
Symptomatic Effectiveness	80.4%	75.2%	>55.0%

Table 9. Single-Procedure Effectiveness (Main Study)

Endpoint	Rate	97.5% KM lower bound	Performance Goal
Single Procedure Effectiveness	71.5%	65.7%	>50.0%

Table 10. AAD-Free Effectiveness (Main Study)

Endpoint	Rate	97.5% KM lower bound	Performance Goal
AAD-Free Effectiveness	64.0%	58.0%	>50.0%

Summary of HSP Substudy Results

Table 11. Primary Effectiveness Endpoint (HSP Substudy, EFF population)

Endpoint	Rate	97.5% KM lower bound
Primary Effectiveness Endpoint	71.8%	57%

Table 12. Primary Safety Endpoint (HSP Substudy, SAF population)

Endpoint	Proportion of Subjects	97.5% Exact Binomial Upper Bound
Primary Safety Endpoint	4.0% (2/50)	13.7%

Table 13. Primary Safety Endpoint Events (HSP Substudy)

Endpoint Criteria	Number of Events	Proportion of Subjects (N=50)
Cardiac tamponade/perforation	1	2.0%
Stroke/cerebrovascular accident	1	2.0%
Total	**2**	**4.0%**

Table 14. Secondary Endpoints (HSP Substudy, EFF population*)

Endpoint	Rate	97.5% KM lower bound
Symptomatic Effectiveness	75.9%	61.5%
Single-Procedure Effectiveness	71.8%	57.0%
AAD-Free Effectiveness	65.8%	50.9%

*Note: Secondary endpoint analysis population based off of the EFF population with additional exclusions related to specific failure definitions per secondary endpoint.

As Treated (AT) Population Analyses

Results from the Main Study and HSP Substudy were used for summary statistical analysis for the As Treated Endpoint subjects that have time averaged power settings of ≥40 Watts vs. <40 Watts in the left atrium.

Table 15. All Endpoint Results for AT population analysis

		Subjects that have time-averaged power settings of <40W in left atrium	Subjects that have time-averaged power settings of ≥40W in left atrium
Primary Effectiveness Endpoint	Rate	67.9%	75.5%
	97.5% KM lower bound	57.4%	69.1%
Primary Safety Endpoint	Rate	5.2 % (5/97)	4.1% (9/222)
	97.5% Exact Binomial Upper Bound	11.6%	7.6%
Secondary Endpoint – Symptomatic Effectiveness	Rate	75.4%	81.5%
	97.5% KM lower bound	65.3%	75.7%
Secondary Endpoint – Single-Procedure Effectiveness	Rate	65.8%	74.5%
	97.5% KM lower bound	55.2%	68.2%
Secondary Endpoint – AAD-Free Effectiveness	Rate	59.4%	67.4%
	97.5% KM lower bound	48.7%	60.7%

Summary of Results Typical Atrial Flutter Objective

Table 16. Ablation of Typical Atrial Flutter Results (Index and Repeat Procedures)

Characteristic	Main Study Cohort (N=284)	HSP Substudy Cohort (N=50)	All Subjects (N=334)
Proportion of subjects treated for concomitant typical AFL with the TactiFlex™ SE catheter.	34.2% (97/284)	32.0% (16/50)	33.8% (113/334)
Proportion of subjects that received CTI ablation with the TactiFlex™ SE catheter.	34.2% (97/284)	32.0% (16/50)	33.8% (113/334)
Proportion of subjects that received CTI ablation that achieved bi-directional block.	97.9% (95/97)	100.0% (16/16)	98.2% (111/113)
Proportion of subjects treated for typical AFL with no recurrent AFL at 3, 6, and 12 months.	91.8% (89/97)	100.0% (16/16)	92.9% (105/113)

Procedural Characteristics

Table 17. Procedural Characteristics

Characteristic	Main Study Cohort (N=284)	HSP Substudy Cohort (N=50)	All Subjects (N=334)
Total initial PV isolation time in minutes			
Mean ± SD (n)	54.1 ± 40.9 (284)	39.6 ± 20.4 (50)	51.9 ± 38.9 (334)
Median (Q1, Q3)	42.0 (29.0, 67.0)	31.5 (25.0, 55.0)	41.0 (27.0, 64.0)
Range (min, max)	(3.0, 322.0)	(5.0, 89.0)	(3.0, 322.0)
Total time for PV ablations in minutes			
Mean ± SD (n)	63.7 ± 43.4 (284)	48.7 ± 23.5 (50)	61.5 ± 41.4 (334)
Median (Q1, Q3)	53.5 (34.0, 80.0)	48.0 (27.0, 62.0)	50.5 (33.0, 76.0)
Range (min, max)	(14.0, 322.0)	(16.0, 118.0)	(14.0, 322.0)
Total procedure time in minutes			
Mean ± SD (n)	134.8 ± 59.4 (284)	121.8 ± 31.0 (50)	132.8 ± 56.2 (334)
Median (Q1, Q3)	121.5 (98.0, 157.5)	118.5 (100.0, 139.0)	119.5 (98.0, 152.0)
Range (min, max)	(56.0, 435.0)	(76.0, 217.0)	(56.0, 435.0)
Total RF time for PV ablation in minutes			
Mean ± SD (n)	22.5 ± 14.9 (282)	16.4 ± 9.2 (50)	21.6 ± 14.3 (332)
Median (Q1, Q3)	18.0 (13.0, 27.0)	13.5 (9.0, 21.0)	17.0 (13.0, 26.5)
Range (min, max)	(3.0, 101.0)	(2.0, 40.0)	(2.0, 101.0)
Total RF time for entire procedure in minutes			
Mean ± SD (n)	25.9 ± 18.7 (283)	19.5 ± 11.0 (50)	25.0 ± 17.9 (333)
Median (Q1, Q3)	21.0 (14.0, 31.0)	17.5 (12.0, 27.0)	20.0 (14.0, 30.0)
Range (min, max)	(4.0, 156.0)	(2.0, 56.0)	(2.0, 156.0)
Left atrial dwell time in minutes			
Mean ± SD (n)	95.3 ± 55.5 (283)	74.6 ± 24.9 (50)	92.2 ± 52.5 (333)
Median (Q1, Q3)	82.0 (60.0, 110.0)	69.5 (58.0, 86.0)	78.0 (60.0, 108.0)
Range (min, max)	(17.0, 385.0)	(39.0, 168.0)	(17.0, 385.0)
Total time, ablation catheter insertion to withdrawal in minutes			
Mean ± SD (n)	101.3 ± 54.5 (284)	78.3 ± 24.0 (50)	97.9 ± 51.7 (334)
Median (Q1, Q3)	86.5 (65.5, 118.5)	73.5 (60.0, 87.0)	85.0 (65.0, 110.0)
Range (min, max)	(25.0, 409.0)	(40.0, 170.0)	(25.0, 409.0)
Total Fluoroscopy time in minutes			
Mean ± SD (n)	9.2 ± 11.7 (283)	9.6 ± 9.5 (50)	9.3 ± 11.4 (333)
Median (Q1, Q3)	5.0 (0.0, 13.0)	8.0 (2.0, 14.0)	5.0 (0.0, 13.0)
Range (min, max)	(0.0, 71.0)	(0.0, 38.0)	(0.0, 71.0)
Total irrigation fluid volume delivered to the patient via the Cool Point Pump in mL			
Mean ± SD (n)	535.1 ± 298.3 (283)	396.5 ± 137.3 (50)	514.3 ± 284.3 (333)
Median (Q1, Q3)	450.0 (346.0, 655.0)	368.5 (297.0, 484.0)	436.0 (336.0, 593.0)
Range (min, max)	(13.0, 2163.0)	(175.0, 716.0)	(13.0, 2163.0)

Planned target CF used anterior wall (g) Mean ± SD (n) Median (Q1, Q3) Range (min, max)	13.1 ± 4.1 (71) 10.0 (10.0, 15.0) (8.0, 20.0)	12.4 ± 3.8 (241) 10.0 (10.0, 15.0) (5.0, 20.0)	12.6 ± 3.9 (312) 10.0 (10.0, 15.0) (5.0, 20.0)
Planned target CF used posterior wall (g) Mean ± SD (n) Median (Q1, Q3) Range (min, max)	12.7 ± 4.1 (71) 10.0 (10.0, 15.0) (5.0, 20.0)	11.7 ± 3.9 (241) 10.0 (10.0, 15.0) (5.0, 20.0)	11.9 ± 4.0 (312) 10.0 (10.0, 15.0) (5.0, 20.0)

Study Conclusion

The TactiFlex™ PAF IDE clinical trial results through 12-month follow up demonstrate that the TactiFlex™ Contact Force Ablation Catheter, Sensor Enabled™, is safe and effective at both <40 and 40-50 Watts for the treatment of drug-refractory recurrent symptomatic paroxysmal atrial fibrillation and concomitant typical atrial flutter.

RF Ablation

For RF ablation, the catheter must be connected to the appropriate input connectors on the TactiSys™ Quartz Equipment, which is then connected to the RF generator. Refer to the TactiSys™ Quartz Equipment User Manual for more information. To complete the electrical circuit, an indifferent electrode must be connected to the reference electrode input on the generator. Circuit impedance prior to RF ablation should be approximately 100 Ohms. Verify that the generator displays a temperature near body temperature after the catheter is inserted into the patient and before applying RF power.

Generator Operation

Refer to the TactiSys™ Quartz Equipment User Manual as well as 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. The TactiSys™ Quartz RF Cable for use with TactiFlex™ and Ampere™ (Model TSQ-RF-TFSE-CBL) cable should be used in place of the TactiSys™ Quartz Ampere RF cable (PN-004 515).

The recommended RF application parameters are provided in the Parameters table under Applying RF Current. Always monitor temperature and impedance rise when using the TactiFlex™ Ablation Catheter, Sensor Enabled™.

Instructions for Use

Refer to the following Instructions for Use when using the TactiFlex™ Ablation Catheter, Sensor Enabled™.

- TactiSys™ Quartz Equipment User Manual
  - The TactiSys™ Quartz RF Cable for use with TactiFlex™ and Ampere™ (Model TSQ-RF-TFSE-CBL) cable should be used in place of the TactiSys™ Quartz Ampere RF cable (PN-004 515).
- EnSite™ X Amplifier Instructions for Use
- EnSite™ X EP System Contact Force Module Instructions for Use
- EnSite™ X EP System TactiFlex™ Ablation Catheter, Sensor Enabled™ Software Module Instructions for Use
- Ampere™ RF Generator Instructions for Use
- Cool Point™ Irrigation Pump Operator Manual

PRECAUTION: Do not use the catheter if not working properly. Check functionality of irrigation and steering mechanism carefully.

Preparing the Catheter for Use

1. Ensure the indifferent electrode is appropriately placed on the patient's body and connected to the RF generator. Only one indifferent electrode should be used for ablation within the recommended ablation settings shown in the General Recommendations table.
2. Obtain vascular access in a large central vessel (e.g. in femoral vein) using aseptic techniques.
3. Remove the catheter from the package while transferring it to the sterile field. Inspect the electrodes and catheter carefully for integrity and overall condition.
4. Connect the catheter's 19-pin electrical connector to the TactiSys™ Quartz Equipment electrical socket.
5. Remove the optical connector protection cap and connect the catheter's optical connector to the optical socket. Do not force connectors or pin damage can occur.

   PRECAUTION: Carefully align the optical connector with the TactiSys™ Quartz Equipment optical socket while firmly pushing in order to ensure connection.
6. Use the 10-pin connector to connect to the EnSite™ X Amplifier.
7. Power ON the generator and TactiSys™ Quartz Equipment and initialize the irrigation pump. Ensure the pump is connected to the RF generator. Refer to the RF generator Operator's Manual for a complete description of generator and pump set-up and communication.
8. Connect the TactiSys™ Quartz Equipment to the RF generator.
9. Connect the irrigation tubing to the Luer fitting of the catheter. A 3-way stopcock may also be used.

   WARNING: Inspect tubing, connections, and saline irrigation for air bubbles prior to and throughout its use in the procedure. Air or bubbles in the saline irrigation may cause emboli.
10. Add heparin to the saline infusion medium according to the patient's anticoagulant condition. Consult the HRS consensus guidelines for anticoagulation strategies [3].
11. Purge the irrigation tube at high flow rate to ensure that no air resides in the tubing system of the catheter. Confirm all irrigation flows through the tip.
12. Verify that the electrode tip temperature is functioning as expected.
13. Once the catheter is purged of all air bubbles, ensure a minimum flow of 2 ml/min throughout the entire procedure to prevent clotting and/or occlusion of the irrigation ports at the catheter's tip.

[3] Calkins, H., Hindricks, G., Cappato, R., Kim, Y.-H., Saad, E. B., Aguinaga, L., Akar, J. G., et al. (2017). 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Heart Rhythm, 14(10), e275–e444. Elsevier BV. Retrieved from http://dx.doi.org/10.1016/j.hrthm.2017.05.012

14. Deflect the catheter in one or both deflectable directions prior to insertion. Do not pull on the saline luer or connector.
    - For the uni-directional catheter, pushing the thumb knob forward causes the distal section of the catheter to deflect. When the thumb knob is pulled back, the distal portion of the catheter will straighten. If needed, use the tension control knob to adjust the steering tension. Out of the package, the knob will be in a locked position.

      NOTE: If necessary, the tension of the uni-directional catheter handle may be adjusted using the adjustable tension control knob. The operator can adjust the tension or unlock by rotating the tension control knob. Use caution when rotating the tension control knob as excessive over-rotation may lead to a loss of tension control.
    - For the bi-directional catheter, pulling one side of the deflection mechanism down from neutral will cause the catheter to deflect in that direction. Pushing the mechanism back to neutral will straighten the catheter. For asymmetric curve designs, the larger curve will have a small bump on the deflection mechanism for easy assessment of the curve type.

      NOTE: The bi-directional handle has an adjustable tension control knob that allows the operator to use the actuator and deflectable section in an unlocked state or adjust the tension to where the actuator and deflectable section are locked in place. The amount of friction increases as the knob is rotated clockwise until it reaches the fully plus (+) position.

      NOTE: Make sure that the locking mechanism on the handle is sufficiently set to hold the curve when the catheter is deflected. If the locking mechanism is insufficiently set it may decrease the catheter stability.

Positioning the Catheter

15. Make sure the catheter is in the neutral (straight) position before insertion. To verify compatibility between sheath and catheter, use caution when first advancing the catheter into the sheath.
16. To avoid occlusion of the irrigation flow from the tip, the catheter must be continuously irrigated when within the vasculature. Irrigation should only be stopped after removal of the catheter from the body.
17. Insert the catheter via the vascular access. Access the left side of the heart only via a transseptal puncture.

    WARNING: To ensure correct use of the force sensor, the distal portion of the catheter should have the tip and one additional electrode outside of the introducer sheath.

    WARNING: To ensure correct use of the intracardiac electrogram signals, the distal portion of the catheter should have the tip and all electrodes outside of the introducer sheath.

    WARNING: When using steerable sheaths, make sure the sheath tip is straight during introduction or withdrawal of the catheter.

    PRECAUTION: The steerability feature of the catheter is designed to operate in a single plane of motion. Attempts to deflect the deflectable section in other planes (e.g. perpendicular to normal steering plane, etc.) may result in damage to the steering mechanism and impaired ability to position the catheter tip as desired by the operator. Do not use catheter with deflectable introducer sheaths that operate in multiple planes of motion. Do not use catheter with deflectable sheaths that may constrain catheter tip deflection through the use of manually operated hemostatic valves.
18. Advance the catheter to the area under investigation. The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy. Use both fluoroscopy and electrograms to aid in proper positioning.

    WARNING: 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 TactiSys™ Quartz Equipment User Manual for instructions on how to zero the contact force reading.
19. Use the deflection mechanism to position the catheter tip in the proper location.

    PRECAUTION: Excessive bending or kinking of the catheter may cause damage to the catheter. Manual pre-bending of the distal curve can impact catheter performance and irrigation flow and may cause patient injury.

    PRECAUTION: Do not use contrast fluid in catheter.

Applying RF Current

20. Ensure the irrigation pump is communicating with the RF generator.
21. Ensure the irrigation pump is set at the flow rate indicated in the table below during power delivery. It is recommended to increase the irrigation to the high flow rate starting up to 3 seconds before the onset of RF energy delivery and maintaining this higher flow rate until 3 seconds after the termination of the energy application.

Table 18. Irrigation

Procedure step	Recommended minimum irrigation flow
Mapping and manipulation	2 ml/min
Ablation	13 ml/min

22. Verify a stable catheter position prior to RF ablation. Refer to the General Recommendations table for contact force recommendations.
23. Ensure the circuit impedance is approximately 100 Ohms upon initiation of RF current.
24. Set the initial power level and the initial temperature limit within the settings outlined in the General Recommendations table under Recommended RF Application Parameters.
25. Start RF energy delivery and ensure that the irrigation pump properly ramps to the recommended flow rate in the General Recommendations table under Recommended RF Application Parameters.
26. If creating a drag lesion, move the catheter in a linear fashion remaining at one site for no longer than the duration outlined in the General Recommendations for Atrial Ablation Table.
27. Monitor the catheter tip temperature during ablation. Monitor the impedance display on the RF generator before, during, and after RF power delivery. If a sudden rise in impedance is noted during RF delivery that does not exceed the preset limit, manually discontinue the power delivery.

    WARNING: The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data.
28. In case of a steam pop, an automatic generator shut off, a sudden rise in temperature or impedance, or an occlusion notice on the pump, discontinue RF power delivery. Remove the catheter for visual inspection and check for coagulum, charring, or other catheter defects.
    - Withdraw the catheter and clean the distal tip with a saline saturated gauze pad to remove any coagulum, if present.

      PRECAUTION: Do not scrub or twist the tip electrode. Damage to the tip electrode or the tip electrode bond may occur.

– Prior to reinsertion, ensure that the irrigation line and ports are not occluded by flushing the catheter at a high flow rate.

PRECAUTION: Do not use if catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve and/or if any of the irrigation ports are blocked.

PRECAUTION: If the Cool Point™ Irrigation Pump alarm sounds, RF energy will be terminated. Communication between the Cool Point™ Irrigation Pump and the Ampere™ RF Generator should be evaluated. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. Remove the catheter from the patient and inspect the catheter and the electrodes. If necessary, clean the electrodes with a sterile saline saturated gauze pad. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion.

29. After RF current is discontinued, ensure the irrigation rate returns to 2 ml/min on the irrigation pump.
30. Power may be increased as needed to the maximum setting to create an effective lesion. Intracardiac electrograms and impedance should be assessed prior to changing the power setting.
31. If the temperature setting is reached but the preset power output is not, it is permissible to increase the temperature setting to the maximum setting (45 °C). Intracardiac electrograms and impedance should be assessed prior to changing the temperature settings.
32. When the procedure is finished, bring the catheter and introducer to their neutral position (straight) before removing them from the patient.
33. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy. The instructions for use is recyclable.

Recommended RF Application Parameters

The recommendations for power settings are presented in the General Recommendations table. Power may be increased as needed to the maximum setting (50 W) to create an effective lesion. These recommendations should be used along with other clinical indicators such as impedance drop, electrogram changes, and tip temperature to guide when to stop RF or move to a new location.

Table 19. General Recommendations for Atrial Ablation

Recommended power setting and duration*	20 W	Up to 60 seconds
	30 W	Up to 50 seconds
	40 W	Up to 20 seconds
	50 W	Up to 10 seconds
Contact force [4]	5 g to 20 g	
Temperature monitoring	37 to 45 °C**	
Irrigation flow rate during RF application	13 ml/min	

* The consecutive duration of an ablation in a given location (focal and drag lesions) should not exceed the recommended time (e.g. at 50 W, the consecutive seconds of ablation energy delivery at a specific site should be 10 seconds or less). Duration should not be used as a sole indicator of when to stop RF application.

** The temperature displayed on the generator does not represent tissue temperature or electrode tissue interface temperature.

WARNING: Application of RF energy outside of the power and duration recommendations may increase the likelihood of steam pop occurrence.

WARNING: Contact force in excess of 20 g may not significantly change the characteristics of lesion formation.

WARNING: Increased contact force may increase the risk for perforation during manipulation of the catheter.

WARNING: Contact force accuracy above 50 g has not been established.

The Ablation Thigh Study Results table provides a quantitative summary of information related to lesion characteristics at varied power levels collected from a GLP thigh study. While this data cannot be directly correlated to lesion formation within human anatomy, it is useful lesion morphology characterization information that could inform clinical use of this catheter.

Table 20. Ablation Thigh Study Results

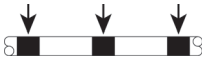
Sample Size	Orientation	Power (W)	Duration (Sec)	Force (g)	Flow Rate (mL/min)	Lesion Depth (mm) Average (±St. Dev.)	Lesion Width (mm) Average (±St. Dev.)
N=45	Parallel	30	50	20	13	8.39 (0.97)	14.52 (1.30)
N=45	Perpendicular	30	50	20	13	8.52 (0.96)	13.87 (1.66)
N=43	Parallel	40	20	20	13	6.67 (0.83)	12.62 (1.23)
N=44	Perpendicular	40	20	20	13	6.86 (0.87)	11.83 (1.31)
N=45	Parallel	50	10	20	13	5.74 (0.70)	11.57 (1.18)
N=45	Perpendicular	50	10	20	13	5.74 (0.89)	10.74 (1.25)

Warranty

Abbott Medical warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the “Expiration” date stated on any product labeling. The authorized uses and approved methods of use of each of our products are set forth in the related “Instructions for Use” that accompany each product. Abbott Medical disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. Abbott Medical’s liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Abbott Medical disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. Abbott Medical neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete Abbott Medical warranty policy available from Abbott Medical or on the back of an Abbott Medical invoice.

[4] Calkins, H., Hindricks, G., Cappato, R., Kim, Y.-H., Saad, E. B., Aguinaga, L., Akar, J. G., et al. (2017). 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Heart Rhythm, 14(10), e275–e444. Elsevier BV. Retrieved from http://dx.doi.org/10.1016/j.hrthm.2017.05.012

Symbols

Symbol	Description
	Sterilized using ethylene oxide
	Consult instructions for use
 medical.abbott/manuals	Follow instructions for use on this website
	Do not use if package is damaged
	Do not reuse
	Use-by date
	Ablation catheter
	Reorder number
	Manufacturer
	Usable Length
	Keep away from sunlight
	Spacing
	Electrodes
	Recommended cables
	Date of Manufacture
	Contents quantity
	Do not resterilize
	Outer Diameter
	Manufacturing Facility
	Keep dry
	Prescription use only

Symbol	Description
	Lot number
	Unique Device Identifier
	Serial number

Abbott Medical
5050 Nathan Lane North
Plymouth, MN 55442 USA
+1 855 478 5833
+1 651 756 5833

St. Jude Medical Costa Rica Ltda.
Edificio #44
Calle 0, Ave. 2
Zona Franca El Coyol
Alajuela
Costa Rica

2022-08
ARTEN600289304 A

600289304

Abbott

ST. JUDE MEDICAL

TactiSys™ Quartz Equipment User Manual Model PN-004 400

INSTRUCTIONS FOR USE
U.S. EDITION

St. Jude Medical
One St. Jude Medical Drive
St. Paul, MN
55117-9913 USA
+1 855 478 5833
+1 651 756 5833
sjm.com

Pat. http://patents.sjm.com

ST. JUDE MEDICAL

ARTEN600027149D~~C~~
2021~~1~~9-05~~4~~

The TactiSys™ Quartz Equipment User Manual is intended to provide the necessary information for proper operation of the TactiSys™ Quartz Equipment hardware and accessories. The TactiSys Quartz Equipment hardware and accessories are indicated for use in conjunction with a ~~TactiCath™~~compatible c~~C~~ontact f~~F~~orce a~~A~~blation c~~C~~atheter. General knowledge of cardiac ablation procedures and an understanding of the features and functions of the TactiSys Quartz Equipment hardware are a prerequisite for proper use.

CAUTION: Do not operate the TactiSys Quartz Equipment hardware without having completely read and understood these instructions.

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

The equipment has been designed and manufactured to meet the requirements of the following safety standards:

IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + A1+2012

IEC 60601-1-2:2014

IEC 60601-2-2:2009 + C1:2014

Introduction

System Description

What Is It?

The TactiSys™ Quartz Equipment is part of a system for percutaneous catheter radiofrequency RF) ablation of atrial cardiac arrhythmias that allows visualization of the contact force between the tip of a compatible~~TactiCath™~~ ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter and the heart wall.

Use of the system to treat a specific cardiac arrhythmia is determined by the indications for use of the ~~TactiCath~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter.

TactiSys™ Quartz Equipment Hardware

The TactiSys Quartz Equipment hardware is a non-sterile active signal and data processing device that interconnects the ~~TactiCath~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter to an external RF generator.

The TactiSys Quartz Equipment hardware collects data from the catheter to compute the force and related information. TactiSys Quartz Equipment hardware operates as a server, sending contact force information to the compatible EnSite™ Contact Force Module (referred later in this document as “Client” .

The TactiSys Quartz Equipment hardware is powered by a mains adapter, which is provided with the device.

Compatible Catheter

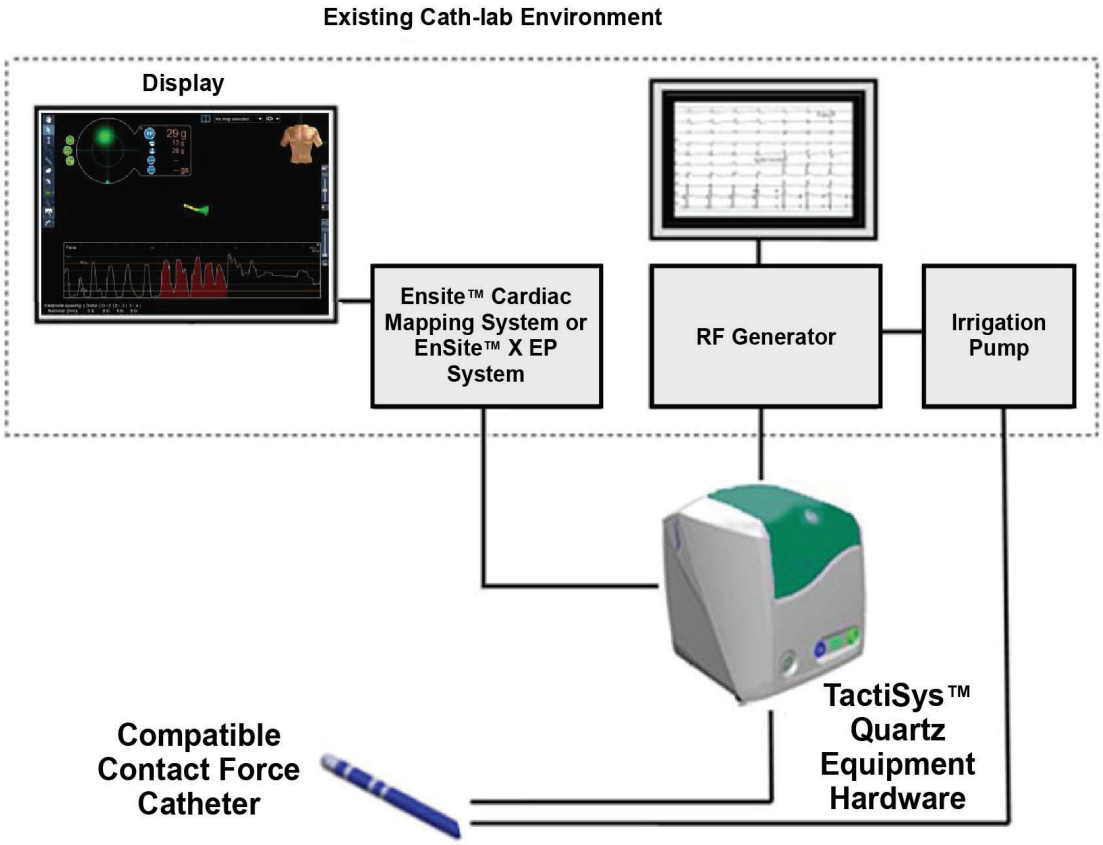
The TactiSys Quartz Equipment is intended to be used with a ~~TactiCath™~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter. The combination of the two devices is referred to as the TactiCath™ Quartz Set.

Related Components

The following additional components are required for RF ablation procedures and to display contact force information:

- RF generator
- Irrigation pump
- Client/ Compatible Electrophysiology System
  - EnSite™ Cardiac Mapping System with EnSite™ Contact Force Module
  - EnSite™ X EP System with EnSite™ X Contact Force Module

The following illustration shows how the devices are interconnected:



Main Functionalities

When used with a ~~TactiCath™~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter, the TactiSys™ Quartz Equipment hardware has the following main functionalities:

- Contact force calculation
- Data transfer to compatible Client~~- ie, EnSite Cardiac Mapping System with EnSite Contact Force Module -~~
- Transmitting intra-cardiac signals for monitoring
- Transmitting pacing signals
- Transmitting RF energy to the cardiac tissue

When used with the TactiSys Quartz Equipment hardware, the EnSite Contact Force Module has the following functionalities:

- Visualization and storage of the force information coming from the catheter tip during mapping and ablation
- Visualization of the contact force signal

System Interconnections and List of Accessories

See Appendix A: System Interconnections for an overview of the TactiSys Quartz Equipment hardware interconnections with other devices in the electrophysiology laboratory.

Indications for Use

TactiSys™ Quartz Equipment and accessories are indicated for use in conjunction with a ~~TactiCath™~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter. TactiSys Quartz Equipment allows the visualization of the force information coming from the catheter tip.

For further information about the ~~TactiCath~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter and its indications for use, please refer to its Instructions for Use IFU .

Important Safety Information

WARNING: A warning indicates that there is a risk of injury to the patient or user.

CAUTION: A caution refers to a condition that may lead to damage or malfunction of the equipment.

NOTE: A note provides additional information.

Physician Training

Cardiac ablation procedures using the TactiCath™ Quartz Set must be performed by physicians who fully understand the working principles of the TactiCath Quartz Set as described in this User Manual. Training on the TactiCath Quartz Set will be provided by St. Jude Medical personnel or by trainers accredited by St. Jude Medical, at the installation of the TactiCath Quartz Set.

Physicians must be familiar with the techniques and be appropriately trained for cardiac mapping and ablation procedures and must be authorized to conduct such procedures according to the laws and guidelines enforced in their country and institutions.

All mapping and ablation procedures must be performed in a fully equipped electrophysiology laboratory that is supported by appropriately trained personnel.

Safety Precautions

CAUTION: This product complies with the Electromagnetic Compatibility Standard IEC 60601-1-2:2014 and needs to be installed and put into service according to Appendix C: Electromagnetic Compatibility.

Certain types of mobile telecommunication equipment could potentially interfere with this product. The separation distances recommended in Appendix C: Electromagnetic Compatibility must be taken into account.

This product should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, this product should be observed to verify normal operation in the configuration in which it will be used.

The use of accessories and cables other than those specified or sold by the manufacturer of this product as replacement parts, may result in increased emissions or decreased immunity of this product.

The equipment contains a lithium battery. Do not attempt to change, recharge, force open, or heat the battery. Do not incinerate equipment.

Electromagnetic Compatibility

WARNING: This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation.

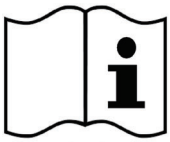
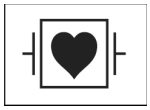
For information about electromagnetic compatibility, see Appendix C: Electromagnetic Compatibility.

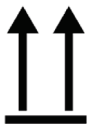
Disposal

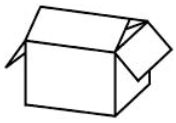
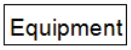
The User Manual is recyclable. Dispose of all packaging materials as appropriate. You can also return the device to the manufacturer for disposal.

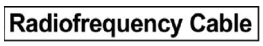
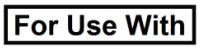
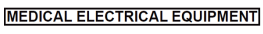
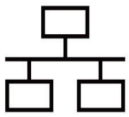
Symbols

The following symbols are used on TactiSys™ Quartz Equipment components:

	Follow instructions for use
	Consult Instructions for Use
	Follow Instructions for Use on this Website
	Caution
	The applied part of the TactiCath™ Quartz Set is type CF for direct cardiac application, and is defibrillator proofed
	Affixed to this device in accordance with European Council Directives 2012/19/EU. These directives call for separate collection and disposal of electrical and electronic equipment. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to St. Jude Medical at the end of its operating life.
	Keep dry

	Fragile; handle with care
	This way up
	Temperature limitation
	Connection of an HF isolated patient circuit
	Power-off
	Power-on
	USB connection
	Equipotential ground connection

	Class II equipment
	Manufacturer
	Authorized Representative in European Community
	Conformité Européenne European Conformity . Affixed in accordance with European Council Directive 93/42/EEC NB 2797 and 2011/65/EU. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.
	Date of Manufacture
	Quantity
	Equipment
	Do not use if package is open or damaged
	Catalogue Number
	Serial Number

	Lot Number
	RF Cable
	Radiofrequency Cable
	For Use With
	CE Mark
	Adapter
	Intertek Safety Agency Certification Mark
	Medical Electrical Equipment
	Computer network
	CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician

Installation

Receiving, Inspecting, and Returning the System

Check for Completeness

After opening the TactiSys™ Quartz Equipment box PN-004 400, check whether you have received all of the following components:

Qty	Name / Description
1	TactiSys™ Quartz Equipment hardware
1	Ethernet cable 3 m
1	Mains adapter
4[a]	Mains cord
1	Equipotential cable
1[b]	User Manual

NOTE:
[a.] US, Australian, EU, and UK mains cords are included in the box.
[b.] Appropriate User Manual depends on your geographic location.

The TactiSys Quartz Equipment hardware shall be used with either of the following RF generator cable, which will be delivered in a separate box:

Catalogue No.	Name / Description
PN-004 515	TactiSys™ Quartz RFadiofrequency cable – Ampere™ Generator
TSQ-RF-TFSE-CBL	TactiSys™ Quartz, TactiFlex™ Radiofrequency cable

The RF generator cable is required to connect the TactiSys Quartz Equipment hardware to the RF generator. An ablation procedure is not possible without the RF generator cable.

Additional accessories may be used in conjunction with the TactiSys Quartz Equipment hardware. A list of optional accessories is given in Appendix B: List of Accessories.

Damage Check and Reporting

When you receive the device, you should check for damage caused during the shipment.

In case the device was damaged during shipment, you should:

- Notify the shipping agent immediately.
- File a damage report to document claims for damages.

Setting up the System

TactiSys™ Quartz Equipment Hardware Installation

Location

The TactiSys Quartz Equipment hardware should be placed outside of the sterile field in the electrophysiology laboratory.

The Client should be placed outside the sterile field in the electrophysiology laboratory or in the control room.

The site controlling the device should have policies in place prescribing the physical safety and security of the devices in the electrophysiology laboratory. For example, physically securing devices and information should include policies that limit physical access, securing equipment in locked rooms, managing access to secured rooms, and restricting the ability to remove devices from a secure area.

WARNING: Do not obstruct the ventilation grid located on the bottom and the top of the TactiSys™ Quartz Equipment hardware case.

CAUTION: To avoid risk of damaging the TactiSys™ Quartz Equipment, make sure that the supporting surface is horizontal, stable, and free from vibrations.

Procedure

To set up TactiSys™ Quartz Equipment, proceed as follows:

1. **Optional:** Assemble the TactiSys Quartz Equipment hardware on the TactiSys™ Quartz ~~Hardware Mount~~Mounting Bracket (see TactiSys Quartz Equipment ~~hardware Mount Assembling~~Mounting Bracket Instructions) and fix the mount close to the electrophysiology laboratory operation table.
2. Connect the mains adapter provided to the appropriate mains cord, and then to the TactiSys Quartz Equipment hardware power socket. Connect the mains cord to the mains power supply.
3. Connect the TactiSys Quartz Equipment hardware to the ~~EnSite™ Cardiac Mapping System~~compatible Client using the Ethernet cable.
4. Connect the green connector of the RF cable to the TactiSys Quartz Equipment hardware RF cable socket, and the other connector into the RF generator.

NOTE: Radiofrequency cable PN-004 515 to be used with TactiCath Contact Force Ablation Catheters
Radiofrequency cable TSQ-RF-TFSE-CBL to be used with TactiFlex Ablation Catheters

5. Connect an equipotential cable to the TactiSys Quartz Equipment hardware equipotential socket.

NOTE: An overview of all the system interconnections can be found in Appendix A: System Interconnections . All combinations of equipment must be in compliance with IEC 60601-1 clause 16) Standard systems requirements. Anyone who interconnects various types of medical equipment configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC 60601-1 clause 16 .

Inspect the Ethernet cable and verify the cable is intact between the TactiSys Quartz System and the ~~Associate Switch for the EnSite Cardiac Mapping System~~Client connection. ~~In addition, verify that all connections to the Associate Switch are connected only to St. Jude Medical-approved devices.~~

NOTE: To prevent dust from contaminating the devices when no optical cables are connected, always cover unused optical cable ports with the protection cap. If there is no or intermittent output of the force sensor, carefully clean the optical connector using a lint-free swab soaked with 99% isopropyl alcohol solution and then dry the optical connector with a new lint-free swab without alcohol.

Use only the mains adapter, cables, and other accessories provided by St. Jude Medical with the TactiSys Quartz Equipment hardware see Appendix B: List of Accessories .

Cleaning and Disinfecting the System

Instructions

To avoid complications due to contamination of the system components, clean and decontaminate them before and after use.

The following table shows how to clean and disinfect the system components:

Do …	Do not …
• Switch the TactiSys™ Quartz Equipment hardware off and disconnect it from mains adapter. • Clean the surfaces with soap and a soft cloth dampened with water. • Prevent moisture from entering the devices. • Use standard hospital cleaning practices.	• Use flammable and explosive agents to clean and disinfect the devices. • Use acetone-containing agents to clean the devices. • Use sterilization methods eg, gas, steam, hot air).

WARNING: Electrical shock hazard: The TactiSys™ Quartz Equipment hardware must be switched off and disconnected from the mains adapter before it is cleaned. No liquid should enter the equipment. Make sure that any remaining liquid on the devices and cables has dried before switching the system on.

TactiSys™ Quartz Equipment Components

Important Information

WARNING: Do not spill liquid on TactiSys™ Quartz Equipment hardware components.

CAUTION: To avoid malfunction, cables and accessories should be visibly inspected prior to use and plug-in/unplug of cables should be carried out with care. Cables with damaged insulation should not be used.

To avoid damage, do not use acetone-containing agents to clean the TactiSys Quartz Equipment hardware. The device surface, including labeled panels, can be cleaned using a soft cloth with soap and water or soft detergents.

To avoid system malfunction, do not connect the interface connector optical fiber for fiber optics to an external voltage source.

Adverse Events

See adverse event information in the IFU of the ~~TactiCath™~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter that you intend to use with TactiSys Quartz Equipment hardware. For a full list of compatible devices, refer to the Compatibility with External Devices section.

NOTE: To maintain system isolation, only medical electrical equipment certified to IEC 60601-1 may be connected to the TactiSys Quartz Equipment hardware. Respect the minimum safety distance between the electrical devices and the patient according to Appendix C: Electromagnetic Compatibility.

The TactiSys™ Quartz Equipment Hardware

Connections of the TactiSys™ Quartz Equipment Hardware to the Other Parts of the System

The TactiSys™ Quartz Equipment Hardware is Connected to the ...	By ...
Compatible Client 26	An Ethernet cable
RF Generator 27	An electrical interface cable connected to the rear panel (24
~~TactiCath™~~Compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter sold separately	The connection cable (3 of the ~~TactiCath™~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter, consisting of one electrical connector 5 and one optical connector 6

NOTE: See Appendix A: System Interconnections for item numbering.

Power Supply

The TactiSys Quartz Equipment hardware is powered by the power cable provided by St. Jude Medical, consisting of mains adapter and mains cord.

TactiSys™ Quartz Equipment Hardware Front Panel

Item number	Part	Function
7	Reset Button	To reset the force values to baseline
8	Power indicator	Lit when the TactiSys™ Quartz Equipment hardware is powered
9	Electrical socket for ~~TactiCath™~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter	Accepts ~~TactiCath™~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter electrical connector
10	Optical socket for ~~TactiCath™~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter	Accepts ~~TactiCath™~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter optical connector

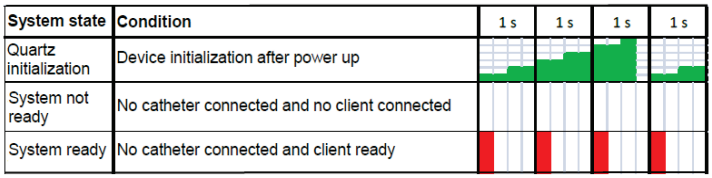
TactiSys™ Quartz Equipment Hardware Rear Panel

Item Number	Part	Function
11	ON/OFF switch	Switch on/off TactiSys™ Quartz Equipment hardware
12	Power socket	Connection to mains power supply via combination of mains cord and mains adapter
13	Ethernet socket	Connection to Client/ EP System ~~(EnSite™ Cardiac Mapping System with EnSite™ Contact Force Module)~~ to display contact force information
14	USB port	Accept mass storage device
15	RF cable socket	Connection to the “catheter” connector of the RF generator
16	X1 serial port	Nonfunctional
17	Equipotential socket	For equalization of the ground potential

Procedures to Operate TactiSys™ Quartz Equipment

Switching on the TactiSys™ Quartz Equipment Hardware

Power on the TactiSys™ Quartz Equipment hardware using the ON/OFF switch located on the rear panel. When the power is turned on, the power indicator on the front panel will become green and the TactiSys Quartz Equipment hardware will load the configuration parameters and run initialization procedures. During this phase, the Reset button slowly flashes green with the pattern shown below, indicating that the TactiSys Quartz Equipment hardware is not ready to start a procedure yet. When the Reset button stops flashing, the TactiSys Quartz Equipment hardware is ready to connect and starts searching for the compatible ~~EnSite™ Contact Force Module~~Client. If the TactiSys Quartz Equipment hardware is ready, but no catheter is connected, the Reset button flashes red.



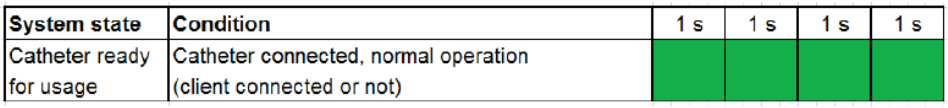
Connecting a ~~TactiCath™~~Compatible Catheter

Refer to the ~~TactiCath~~compatible catheter Instructions for Use for instructions to connect the catheter to the TactiSys Quartz Equipment.

Starting a~~n~~ Compatible EnSite™ Contact Force Module Procedure

Refer to the ~~EnSite™ Contact Force Module~~compatible Client Instructions for Use for information about how to start a procedure.

When the catheter is connected and recognized, the Reset button is green.



Replacing a ~~TactiCath™~~Compatible Catheter

It is not necessary to interrupt the current procedure to replace the catheter. To replace the catheter currently connected to the TactiSys™ Quartz Equipment hardware, proceed as follows:

1. Unplug the catheter you wish to replace.
   The message “No Contact Force catheter connected...” will be displayed on the ~~EnSite™ Contact Force Module~~compatible Client.

2. Plug in a new catheter and return to the procedure.

CAUTION: If no valid catheter is connected, a message describing the reason for this invalidity will appear and the Reset button is red.

System state	Condition	1 s	1 s	1 s	1 s
Catheter malfunction	Catheter connected, no force reading during procedure (client connected or not)				

NOTE: Data collection for inclusion in the procedure report will continue unless the procedure is closed in the EnSite™ Contact Force module. Starting a new procedure will cause the subsequent procedure data to be entered in a new report.

Downloading Log Files from the TactiSys™ Quartz Equipment Hardware

Log files can be retrieved from TactiSys™ Quartz Equipment hardware through its USB port.

Method to download all log files stored on the TactiSys Quartz Equipment hardware:

1. Introduce a USB storage device in the TactiSys Quartz Equipment hardware USB port.
2. Press on the Reset button for 3 seconds or more no Client and no catheter connected .
3. Active downloading is signaled to the user by a sound and Reset button light.
4. Successful or unsuccessful completion of file download is signaled to the user by two different sound patterns and Reset button light colors.

NOTE: Log files are for maintenance purposes only.

Reset button light flashing scheme during log file download:

System state	Condition	1 s	1 s	1 s	1 s
USB upload	USB disk upload in progress (no catheter connected and no client connected)				

Technical Specifications

Inspections and Repairs

To ensure device safety, maintenance, repairs, and technical safety inspections of the TactiSys™ Quartz Equipment and its accessories must only be performed by St. Jude Medical or an agent which has been expressively authorized by St. Jude Medical.

Maintenance

Hardware Maintenance

CAUTION: Yearly maintenance shall be performed by St. Jude Medical qualified personnel or by maintenance personnel accredited by St. Jude Medical. This maintenance includes cleaning of the optical connector and verification of device performance.

You should never perform hardware maintenance other than cleaning and disinfecting the system see Cleaning and Disinfecting the System , except the routine maintenance described below. If any hardware problem occurs, contact St. Jude Medical.

The TactiSys™ Quartz Equipment hardware contains a lithium battery for keeping the date and time in the embedded PC-board. There is a danger of battery explosion if it is incorrectly installed. Do not attempt to recharge, force open, or heat the battery. In case the date and time are lost, please contact St. Jude Medical for battery replacement.

Routine Maintenance

The routine maintenance should be performed monthly according to the following procedure:

- Clean and disinfect the system. Please refer to Cleaning and Disinfecting the System for cleaning and disinfecting instructions.
- Inspect carefully the mains cord for any signs of mechanical damage to cable or connector. If damaged, replace with a genuine St. Jude Medical replacement part. Do not attempt to repair.
- Inspect any other electrical or optical cable assembly for any signs of mechanical damage to cable or connector. If damaged, replace with a genuine St. Jude Medical replacement part. Do not attempt to repair.
- Inspect the TactiSys™ Quartz Equipment hardware plastic cover for any signs of mechanical damage, such as cracks or holes. If damaged, contact your vendor technical support as soon as possible. Do not attempt to repair.

Software Maintenance

The software maintenance is performed by St. Jude Medical qualified personnel or by maintenance personnel accredited by St. Jude Medical.

Maintenance Contract

If desired, a maintenance contract can be arranged with the manufacturer. This maintenance contract will include inspection of technical safety.

TactiSys™ Quartz Equipment Hardware Specifications

General

Mains Adapter

Input Voltage: 100 – 240 VAC

Input Frequency: 50 – 60 Hz

Input Current: 1.1A

Output Voltage: 12V VDC

Output Current: 3.8 A

TactiSys™ Quartz Equipment Hardware Power Supply from Mains Adapter

Input voltage: 12 V⎓

Input current: 1.5 A

Protection

Protection against electrical shock: Class II

Applied part ~~TactiCath™~~compatible ~~C~~contact ~~F~~force ~~A~~ablation ~~C~~catheter): CF, protected against the effects of defibrillation

Degree of protection against ingress of solids and water: IP20

Electromagnetic Compatibility EMC)

The equipment complies with IEC 60601-1-2:2014 and the relevant particular standards for emission and immunity. See Appendix C: Electromagnetic Compatibility.

Physical Specifications

TactiSys™ Quartz Equipment hardware:

- Height: 235 mm
- Width: 260 mm
- Depth: 185 mm
- Weight: 4.2 - 4.6 kg

System Performances with TactiCath™ Contact Force Ablation Catheters

F. total

Total force display range: 0 to 990 g

Total force display resolution: 1 g

Total force accuracy during mapping:

- F < 20 g: ± 3 g
- 20 g ≤ F ≤ 150 g: ±15% of F
- F > 150 g: unspecified

Total force offset during RF delivery:

- F ≤ 150 g: ±10 g

F. lateral

Lateral force display range: 0 to 990 g

Lateral force display resolution: 1 g

F. axial

Axial force display range: 0 to 990 g

Axial force display resolution: 1 g

System Performances with TactiFlex™ Ablation Catheter

F. total

Total force display range: 0 to 990 g

Total force display resolution: 1 g

Total force accuracy during mapping:

- 5 g < F < 10 g: ± 3 g
- 10 g ≤ F ≤ 50 g: ±30% of F
- F > 50 g: unspecified

Total force offset during RF delivery:

- F < 50 g: ±10 g

F. lateral

Lateral force display range: 0 to 990 g

Lateral force display resolution: 1 g

F. axial

Axial force display range: 0 to 990 g

Axial force display resolution: 1 g

Compatibility with External Devices

Compatible Catheter

For the list of all compatible contact force ablation catheter models compatible with the TactiSys™ Quartz Equipment, please refer to the appropriate compatible contact force ablation catheter IFU.

- TactiCath™ Contact Force Ablation Catheter
  - TactiCath™ Quartz Contact Force Ablation Catheter
  - TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™
- TactiFlex™ Ablation Catheter, Sensor Enabled™

Compatible RF Generator

St. Jude Medical Ampere™ RF Generator

Compatible ~~Mapping System~~Client/ EP System

- EnSite™ Cardiac Mapping System with EnSite™ Contact Force Module
- EnSite™ X EP System with EnSite™ X Contact Force Module

Environmental Conditions

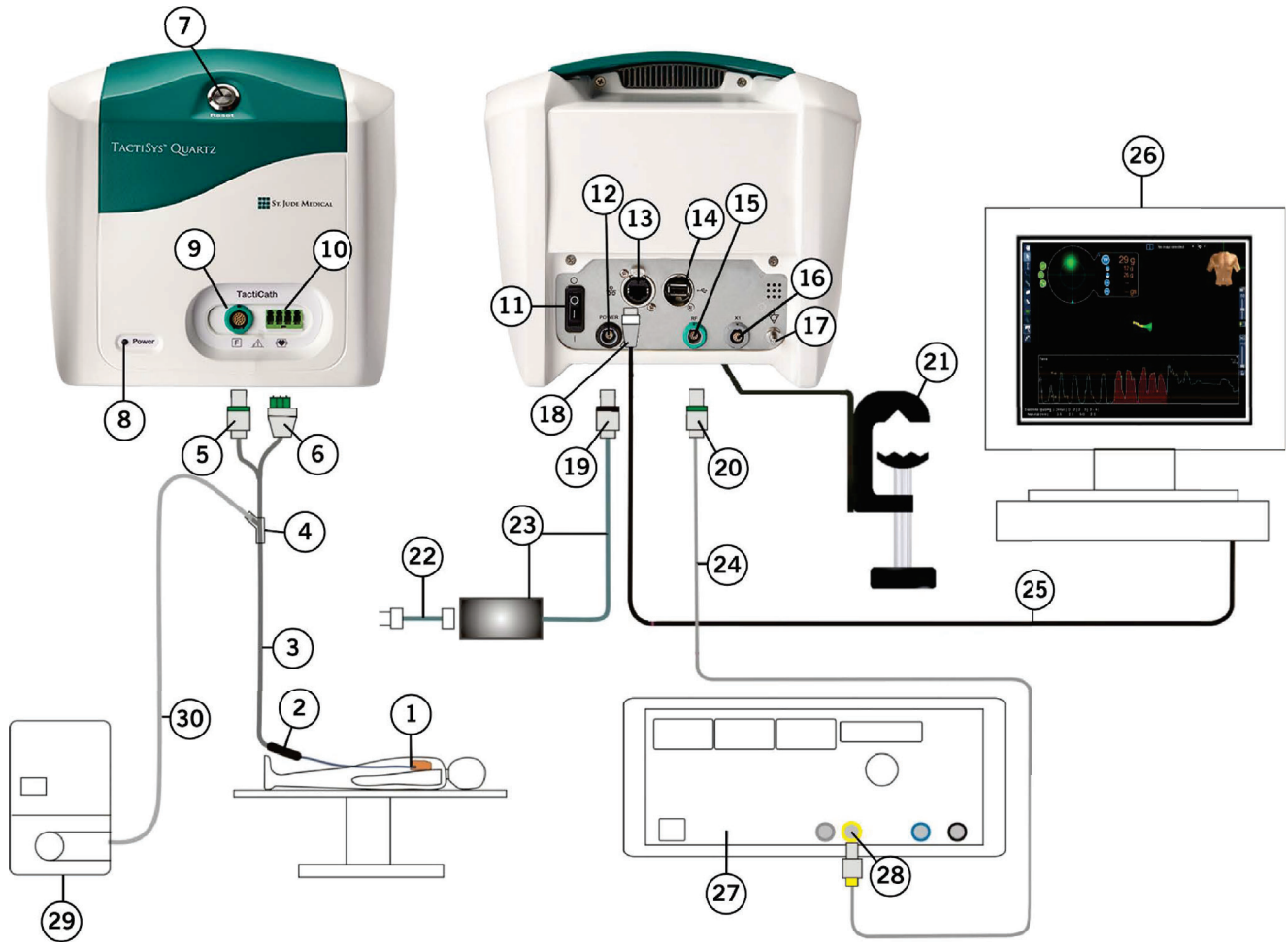
Operating Conditions

Ambient air temperature:	+10 to +30 °C
Relative humidity:	15 to 80%
Ambient pressure:	525 to 800 mmHg 700 to 1060 hPa
Thermocouple:	Type T
Irrigation flow temperature:	+15 to +25 °C

Transport and Storage Conditions

Ambient air temperature:	-10 to +50 °C
Relative humidity:	15 to 95%
Ambient pressure:	375 to 800 mmHg 500 to 1060 hPa

Appendix A: System Interconnections



List of Connections

The item numbers correspond with the numbers in the illustration.

Item Number	Name / Description
1	~~TactiCath™ Contact Force Ablation Catheter~~Compatible contact force ablation catheter distal tip
2	~~TactiCath™ Contact Force Ablation Catheter~~Compatible contact force ablation catheter handle
3	~~TactiCath™ Contact Force Ablation Catheter~~Compatible contact force ablation catheter proximal connection cable
4	~~TactiCath™ Contact Force Ablation Catheter~~Compatible contact force ablation catheter irrigation Luer
5	~~TactiCath™ Contact Force Ablation Catheter~~Compatible contact force ablation catheter electrical connector

Item Number	Name / Description
6	~~TactiCath™ Contact Force Ablation Catheter~~Compatible contact force ablation catheter optical connector
7	Reset button
8	Power indicator
9	Electrical socket for the ~~TactiCath™ Contact Force Ablation Catheter~~Compatible contact force ablation catheter
10	Optical socket for the ~~TactiCath™ Contact Force Ablation Catheter~~Compatible contact force ablation catheter
11	ON/OFF switch
12	Power socket
13	Ethernet socket
14	USB port
15	RF cable socket
16	X1 serial port not supported)
17	Equipotential socket
18	Ethernet cable connector
19	Mains adapter connector
20	RF cable connector
21	TactiSys™ Quartz Equipment Mounting bracket and bedrail clamps
22	Mains cord
23	Mains adapter
24	RF cable
25	Ethernet cable
26	~~EnSite™ Cardiac Mapping System with EnSite™ Contact Force Module~~Compatible Client
27	RF Generator
28	RF Generator Catheter socket
29	Irrigation Pump
30	Irrigation Tube

Appendix B: List of Accessories

~~Compatible TactiCath™ Contact Force Ablation Catheter~~

~~For the list of all TactiCath™ Contact Force Ablation Catheter models compatible with the TactiSys™ Quartz Equipment, please refer to the appropriate TactiCath Contact Force Ablation Catheter IFU.~~

Optional Accessories of TactiSys™ Quartz Equipment Hardware and their Relevant Catalogue Numbers

Catalogue No.	Name / Description
PN-004 515	TactiSys™ Quartz R~~F~~adiofrequency cable – Ampere™ Generator (when used with TactiCath Contact Force Ablation Catheter
PN-004 510	Ethernet cable 20 m
PN-004 516	Ethernet cable 10 m
TSM-ABV-GBL	TactiSys™ Quartz Equipment Mounting Bracket (above-below configuration
TSM-BSD-GBL	TactiSys™ Quartz Equipment Mounting Bracket side-to-side configuration)
BED-CLP-WE	Bedrail Clamp Western Europe)
BED-CLP-UK	Bedrail Clamp (UK)
BED-CLP-JPN	Bedrail Clamp (Japan)
BED-CLP-NA	Bedrail Clamp (North America
TSQ-RF-TFSE-CBL	TactiSys™ Quartz, TactiFlex™ Radiofrequency cable when used with TactiFlex Ablation Catheters)

Appendix C: Electromagnetic Compatibility

Electromagnetic Emissions

The TactiCath™ Quartz Set is intended for use in the electromagnetic environment specified below. The customer or the user of the TactiCath Quartz Set should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The TactiCath™ Quartz Set uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The TactiCath™ Quartz Set is suitable for use in all establishments other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity

The TactiCath™ Quartz Set is intended for use in the electromagnetic environment specified below. The customer or the user of the TactiCath Quartz Set should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge ESD EN61000-4-2 IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN61000-4-4 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN61000-4-5 IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variation on power supply input lines IEC 61000-4-11	0%U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; for 5 sec @ 60 Hz 300 cycles) 0% U_T; 250/300 cycles	100% dropout in VNOM for 0.5 cycle at listed phase angles 100% dropout in VNOM for 1 cycle at 0° 30% dropout in VNOM for 25/30 cycles at 0° 100% dropout in VNOM for 5 sec 100% interrupt in VNOM for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TactiCath™ Quartz Set requires continued operation during power mains interruptions, it is recommended that the TactiCath Quartz Set be powered from an uninterruptible power supply or a battery.
Power frequency 50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

RF Portable Equipment

The TactiCath™ Quartz Set is intended for use in the electromagnetic environment specified below. The customer or the user of the TactiCath Quartz Set should assure that it is used in such an environment. To avoid possible interference with any electromagnetic emitters that do not conform with this environment, ensure that these emitter sources are disabled or removed from the environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Portable and mobile RF communications equipment should be used no closer to any part of the TactiCath™ Quartz Set, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms [V_1 = 3]	**Recommended Separation Distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [1.2]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m [E_1 = 3]	$d = [1.2]\sqrt{P}$ 800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$ $d = [2.3]\sqrt{P}$
			where P is the maximum output power rating of the transmitter in Watts W according to the transmitter manufacturer and d is the recommended separation distance in Metres m . Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Portable and mobile RF communications equipment should be used no closer to any part of the TactiCath™ Quartz Set, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter			
Immunity to Proximity Fields from RF wireless communications equipment IEC 60601-1-2 Clause 8.10	385-5785 MHz	9-27 V/m	Per IEC 60601-1-2 Per Table 9 of Standard
U_T is the AC mains voltage prior to application of the test level.			

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio cellular/cordless telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TactiCath™ Quartz Set is used exceeds the applicable RF compliance level above, the TactiCath Quartz Set should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the TactiCath Quartz Set.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Recommended Separation Distances

This topic includes recommended separation distances between portable and mobile RF communications equipment and the device.

The TactiCath™ Quartz Set is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TactiCath Quartz Set can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment transmitters and the TactiCath Quartz Set as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.117	0.117	0.233
0.10	0.369	0.369	0.737
1	1.167	1.167	2.33
10	3.69	3.69	7.37
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres m can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W according to the transmitter manufacturer.			

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.