ST. JUDE MEDICAL

TactiSys™ Quartz Equipment User Manual Model PN-004 400

INSTRUCTIONS FOR USE
U.S. EDITION

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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™ Contact Force Ablation Catheter. 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

Table of Contents

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 TactiCath™ Contact Force Ablation 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 Contact Force Ablation Catheter.

TactiSys™ Quartz Equipment Hardware

The TactiSys Quartz Equipment hardware is a non-sterile active signal and data processing device that interconnects the TactiCath Contact Force Ablation 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 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

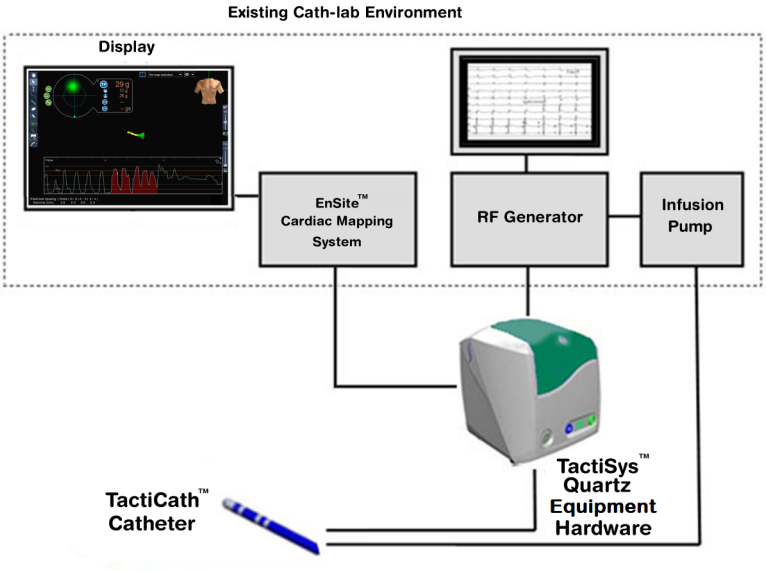
The TactiSys™ Quartz Equipment is intended to be used with a TactiCath™ Contact Force Ablation Catheter. The combination of the two devices is referred to as the TactiCath™ Quartz Set.

Related Components

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

- RF generator
- Irrigation pump
- EnSite™ Cardiac Mapping System with EnSite™ Contact Force Module

The following illustration shows how the devices are interconnected:



Main Functionalities

When used with a TactiCath™ Contact Force Ablation Catheter, the TactiSys™ Quartz Equipment hardware has the following main functionalities:

- Contact force calculation
- Data transfer to 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 “System Interconnections” on page 25 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™ Contact Force Ablation Catheter. TactiSys Quartz Equipment allows the visualization of the force information coming from the catheter tip.

For further information about the TactiCath Contact Force Ablation 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 the USA and their 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 “Electromagnetic Compatibility (EMC)”.

Certain types of mobile telecommunication equipment could potentially interfere with this product. The separation distances recommended in “Electromagnetic Compatibility (EMC)” 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.

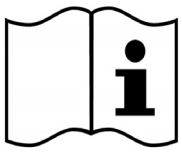
For information about electromagnetic compatibility, see “Electromagnetic Compatibility” on page 29.

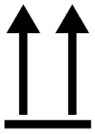
Disposal

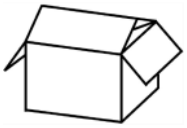
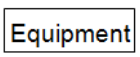
The User Manual is recyclable. Dispose of all packaging materials as appropriate. You can also return the device to the manufacturer for disposal.

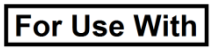
Symbols

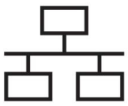
The following symbols are used on TactiSys™ Quartz Equipment components:

	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.
	CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician
	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
	Conformité Européenne (European Conformity). Affixed in accordance with European Council Directive 93/42/EEC (NB 0086) 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
	For Use With
	CE Mark
	Pack
	Adapter
	Intertek Safety Agency Certification Mark
	Medical Electrical Equipment

	Computer network

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 the following RF generator cable, which will be delivered in a separate box:

Catalogue No.	Name / Description
PN-004 515	TactiSys™ Quartz RF cable – Ampere™ Generator

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 “List of Accessories” on page 27.

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 (see TactiSys Quartz Equipment hardware Mount Assembling 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 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.
5. Connect an equipotential cable to the TactiSys Quartz Equipment hardware equipotential socket.

WARNING: An overview of all the system interconnections can be found in “System Interconnections” on page 25. 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. 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 “List of Accessories” on page 27).

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™ Contact Force Ablation Catheter that you intend to use with TactiSys Quartz Equipment hardware.

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 “Electromagnetic Compatibility” on page 29.

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 ...
Client (26)	An Ethernet cable
RF Generator (27)	An electrical interface cable connected to the rear panel (24)
TactiCath™ Contact Force Ablation Catheter (sold separately)	The connection cable (3) of the TactiCath™ Contact Force Ablation Catheter, consisting of one electrical connector (5) and one optical connector (6)

NOTE: See “System Interconnections” on page 25 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™ Contact Force Ablation Catheter	Accepts TactiCath™ Contact Force Ablation Catheter electrical connector
10	Optical socket for TactiCath Contact Force Ablation Catheter	Accepts TactiCath™ Contact Force Ablation 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 (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 EnSite Contact Force Module. If the TactiSys Quartz Equipment hardware is ready, but no catheter is connected, the Reset button flashes red.

System state	Condition	1 s	1 s	1 s	1 s
Quartz initialization	Device initialization after power up				
System not ready	No catheter connected and no client connected				
System ready	No catheter connected and client ready				

Connecting a TactiCath™ Catheter

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

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

System state	Condition	1 s	1 s	1 s	1 s
Catheter ready for usage	Catheter connected, normal operation (client connected or not)				

Starting an EnSite™ Contact Force Module Procedure

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

Replacing a TactiCath™ 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.
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 encrypted and are for maintenance purposes only. They contain no information accessible to the user.

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, only St. Jude Medical (or an agent who has been expressively authorized by St. Jude Medical) is to complete maintenance, repairs, and technical safety inspections of the TactiSys Quartz Equipment and its accessories.

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” on page 12), 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” on page 12 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™ Contact Force Ablation 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 “Electromagnetic Compatibility” on page 29.

Physical Specifications

TactiSys™ Quartz Equipment hardware:

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

System Performances

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

Compatibility with External Devices

Compatible RF Generator

St. Jude Medical Ampere™ RF Generator

Compatible Mapping System

EnSite™ Cardiac Mapping System with EnSite™ Contact Force Module

Environmental Conditions

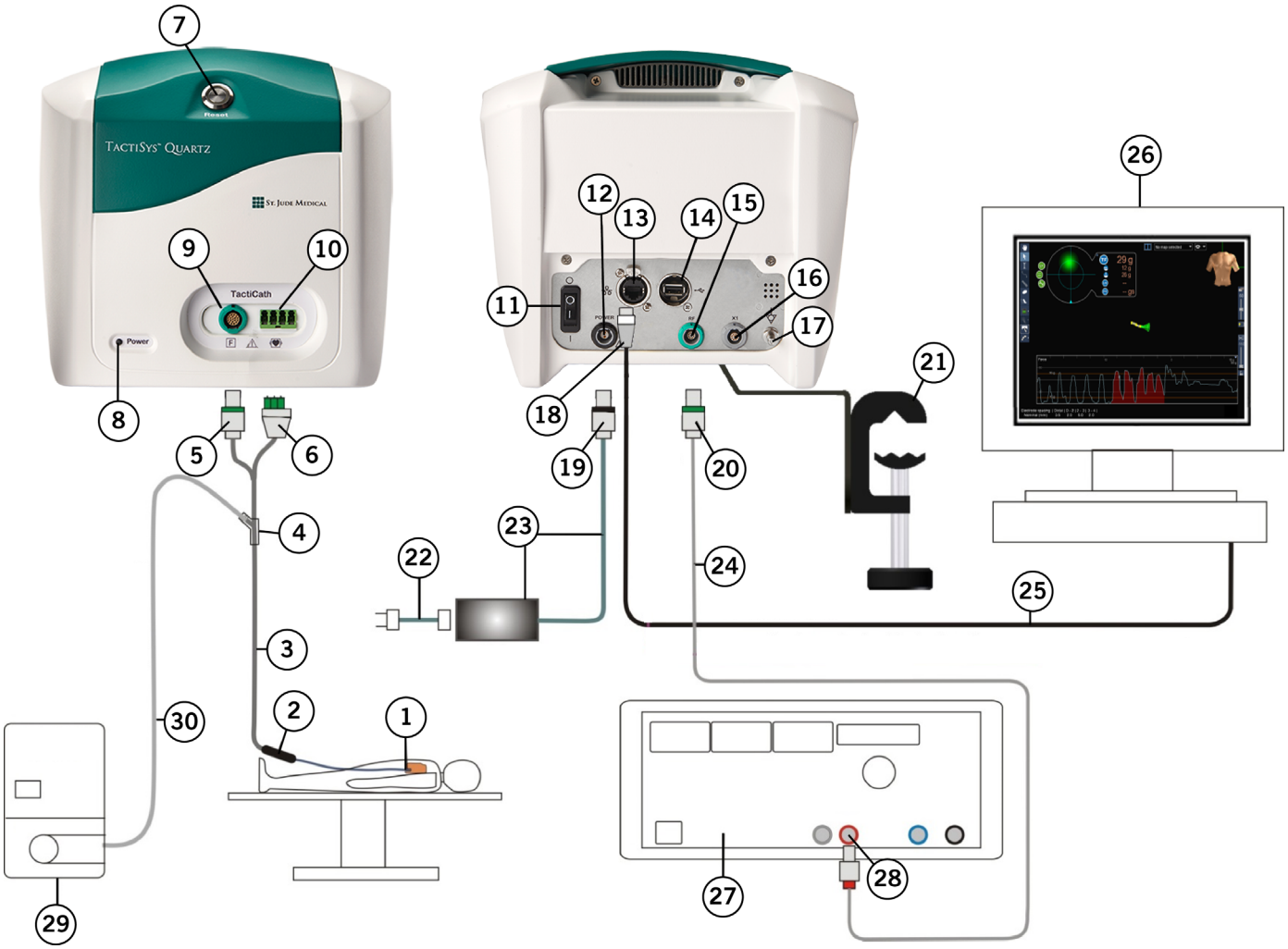
Operating Conditions

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)

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 distal tip
2	TactiCath™ Contact Force Ablation Catheter handle
3	TactiCath™ Contact Force Ablation Catheter proximal connection cable
4	TactiCath™ Contact Force Ablation Catheter irrigation Luer
5	TactiCath™ Contact Force Ablation Catheter electrical connector
6	TactiCath™ Contact Force Ablation Catheter optical connector
7	Reset button
8	Power indicator
9	Electrical socket for the TactiCath™ Contact Force Ablation Catheter

10	Optical socket for the TactiCath™ 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
27	RF Generator
28	RF Generator Catheter socket
29	Irrigation Pump
30	Irrigation Tube

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 Equipment Hardware RF cable – Ampere™ Generator
PN-004 510	Ethernet cable 20 m
PN-004 516	Ethernet cable 10 m
TSM-ABV-GBL	TactiSys™ Quartz Equipment Hardware Mounting Bracket (above-below configuration)
TSM-BSD-GBL	TactiSys™ Quartz Equipment Hardware Mounting Bracket (side-to-side configuration)
BED-CLP-NA	Bedrail Clamp (North America)

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. 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
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 $d = [\frac{7}{E_1}]\sqrt{P}$ $d = [2.3]\sqrt{P}$

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.			
			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 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)
NOTE: 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 2,5 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	1.67	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.