CareCenter MD™
Product Information and Safety

70-00663-01 D

This booklet contains important safety and care information.

Contents

Caution: Read all instructions.

See the *CareCenter MD™ User's Guide* for all other instructions and important safety information. Read all instructions before using CareCenter MD. A complete manual set is available through the application after the software is installed.

CARDIAC science™

AT THE HEART OF SAVING LIVES®

Cardiac Science provides customer service and technical support.

- To order additional product or accessories, contact Customer Care.
- For assistance with the product or installation, contact Technical Support.

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Description

The Cardiac Science CareCenter MD is a PC-based system for acquisition and evaluation of 12-channel ECG both at rest and during exercise in hospitals and physician offices.
CareCenter MD is a diagnostic device capable of ECG monitoring; ST analysis and arrhythmia detection; generation, review, and storage of resting ECG and stress reports; interpretation of adult resting ECG; and select exercise device control. The product consists of software for a user-provided PC running a Windows operating system and a means to acquire ECG data. There are two data acquisition devices, which differ in their means of communication with the PC. The first device utilizes a hardwired USB connection to a proprietary USB data acquisition module, while the other device utilizes a *Bluetooth®* wireless connection to a proprietary *Bluetooth®* data acquisition module. Approved serial devices such as non-invasive blood pressure measurement will be supported for stress testing.

Intended use

The Cardiac Science CareCenter MD device is intended for use on adult and pediatric patients in a clinical setting by trained personnel under the supervision of a licensed healthcare practitioner. It is designed to acquire, display, process, record, analyze and output 12 lead ECG data during periods of physiological stress, induced through exercise or pharmacological means or during resting ECG testing. The device may interface with external devices, including a treadmill or ergometer for dynamic exercise evaluation, non-invasive blood pressure equipment, and computer communications equipment.

The interpretation program is intended to provide diagnostic support to the physician for evaluation of adult ECG rhythm and morphology. No automatic interpretation of resting ECGs is provided for pediatric populations. Interpretive statements should be overviewed and approved by trained physicians.

The device is not intended to be used as a vital signs physiological monitor. The CareCenter MD is not intended to be used as a transport device.

WARNING! Follow all instructions

You are responsible for the safety of your device. Please follow all safety instructions.

Indications for use

The Cardiac Science CareCenter MD is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner on adult and pediatric populations. The device is designed to acquire, display, process, record, analyze and output 12 lead ECG data during periods of physiological stress, induced through exercise or pharmacological means or during resting ECG testing. In addition, the CareCenter MD provides interfaces for acquiring physiological data from ancillary devices (non-invasive blood pressure) and records ECG in real time with and without arrhythmia detection.

The system provides automatic interpretation of resting ECG on adult populations. No automatic interpretation of resting ECGs is provided for pediatric populations. Interpretive statements should be overviewed and approved by trained physicians.

The CareCenter MD may provide interfaces for the control of external devices such as a treadmill or an ergometer, and for communicating with centralized computer systems via a network. The device is intended to provide non-diagnostic patient data management functions as both a self-contained, stand-alone application and by interfacing with Electronic Medical Records systems.

The device is not intended to be used as a vital signs or long term physiological monitor. The CareCenter MD is not intended to be used as a transport device

Contraindications

WARNING! Follow all instructions.

The CareCenter MD and CareCenter MD acquisition recording devices are products of risk class IIa according to Annex IX of the guideline 93/42/European Economic Community for medical devices. The CareCenter MD recording devices are NOT allowed for applications with direct contact to the heart or the central nervous system. Follow all instructions in the manuals for the acquisition devices.

CareCenter MD is not compatible with the following products installed on the same computer:

Manufacture	Product
Medikro	Spiro 2000

Warnings and cautions

Safety alert descriptions

The symbols shown below identify potential hazard categories. The definition of each category is as follows:

WARNING!

This alert identifies hazards that may cause serious personal injury or death.

Caution

This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

General warnings and cautions

This section lists general warnings and cautions. Those pertaining to specific functions and procedures are included in the text where appropriate.

WARNING! Equipment compatibility.

Use only Cardiac Science approved and specified parts, accessories and any consumables. Use of other parts can degrade performance and/or safety and may void warranty or contract coverage.

Caution: Restricted use.

U. S. Federal Law restricts this device to sale by or on the order of a physician.

Caution: Misdiagnosis

While the HES program shows good performance, the automatic evaluation is only an aid for the physician. Electronic transmissions, chart recorders and other printing devices may distort the ECG. The correctness of the results cannot be guaranteed and may be affected by incorrect or corrupted data. Therefore, a physician must check and confirm every measurement results and diagnoses. Use under clinical supervision only.

Caution: Patient safety.

CareCenter MD and the CareCenter MD Online feature are not intended for use as remote patient monitors. CareCenter MD Online is for reference only.

Caution: Incompatible software.

To reduce software conflicts, follow all instructions in the license agreement.

Caution: Not for medical transport.

This system is not intended to be used in medical transport environments.

Caution: Unexpected system behavior.

Cardiac Science cannot guarantee system behavior when automatic updates of third-party software occurs. Observe the behavior of the system and consult Technical Support, if required.

Caution: Unexpected system behavior.

Cardiac Science cannot guarantee system behavior when third-party software is installed on the system. Before loading any third-party software contact Cardiac Science for a list of approved third-party software.

Caution: Unexpected system behavior.

Software viruses can harm computer programs. Cardiac Science recommends periodically performing a virus scan when CareCenter MD is not active. Virus scanning is especially important if CareCenter MD is connected to a network.

Electrical safety

The CareCenter MD is a medical electrical device. It meets all requirements for the safety of medical electrical devices, in particular the requirements for IEC/EN 60601-1, IEC/EN 60601-1-2, and IEC/EN 60601-1-2-25.

The CareCenter MD is intended to be connected to a personal computer through a USB port. The personal computer and the peripheral devices (monitor, and printer) connected to the CareCenter MD should be certified to the appropriate safety standards for non-medical electrical equipment and must be located outside the patient environment.

If the personal computer or peripherals are located within the patient environment, an isolation transformer must be used to comply with IEC/EN 60601-1-1.

For...	Isolation transformer status
CareCenter MD	Cardiac Science does not provide isolation transformers. The customer is responsible for providing appropriate isolation in the patient vicinity.
Quinton 9500 with CareCenter MD	Cardiac Science provides an isolation transformer.
Quinton 9550 with CareCenter MD	Cardiac Science provides an isolation transformer.

The CareCenter MD is a CF type applied part which isolates the patient from the computer.

WARNING! Electrical safety.

All non-medical devices should conform to applicable safety standards.

WARNING! Electrical safety.

If this device is used with a personal computer operating at a MAINS voltage greater than 120V then additional isolation needs to be incorporated.

WARNING! Electrical safety.

Improperly grounded equipment may cause electrical shock. Use only the power cords supplied by Cardiac Science and plug the system into a properly grounded power outlet only.

WARNING! Electrical safety.

Damaged power cords may cause electrical shock. Before using the system, check for power cords that may be broken or frayed. Do not use any system with damaged power cords and remove power from a system with damaged power cords.

WARNING! Electrical safety.

If your system is equipped with an isolation transformer, replacing fuses with the incorrect rating can cause electrical shock. Note the fuse rating. Always replace the fuses with fuse of the same rating.

Caution: Electrical safety.

An inappropriate or defective patient cable can damage the amplifier circuit and prevent the display of patient reaction. Use only Cardiac Science-supplied patient cables and check the cables for damage before each use.

Caution: Electrical safety.

Do not put the multiple socket outlet on the floor.

Caution: Electrical safety.

Do not exceed the multiple socket board's permissible amperage.

Caution: Electrical safety

If not all the electrodes are applied to the patient, place the electrodes that are not in use in such a way that they cannot come into contact with a metallic part. Do not touch the electrodes which have not been applied.

Caution: Electrical shock

Touching an exposed battery has the risk of electrical shock. Always ensure the battery compartment for the wireless acquisition device is properly closed during use.

Caution: Equipment damage

To prevent injury and damage to the equipment from leaking batteries, remove the batteries from the battery compartment if the wireless acquisition device is not going to be used for a long period of time.

Defibrillation safety

WARNING! Shock and possible equipment damage

Disconnect all non-defibrillator-proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

Caution: Equipment damage

To prevent injury and damage to the equipment use only equipment provided by Cardiac Science.

Radio frequency

Radio frequency radiation exposure Information: The radiated output power of the device is far below the FCC radio frequency exposure limits. Nevertheless, the device shall be used in such a

manner that the potential for human contact during normal operation is minimized.

NOTICE: This device complies with Part 15 of the FCC Rules [and with RSS-210 of Industry Canada]. Operation is subject to the following two conditions:

1. this device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

NOTICE: Changes or modifications made to this equipment not expressly approved by Cardiac Science may void the FCC authorization to operate this equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Ambient conditions

WARNING! Explosion

Operating electrical equipment in an environment containing explosive gases can trigger an explosion. Use this equipment only in a well-ventilated, ambient environment. Do not use the acquisition devices or any information technology (computer, printer, monitor) in an explosion-endangered or oxygen-enriched environment. The acquisition devices are not classified AP or APG.

Caution: Proper system operation

Use the acquisition devices within the allowable temperatures only. Condensation may build up on a device brought into a warm environment from a cold environment. Ensure there is no condensation before using the device.

Operations

WARNING! Patient injury.

Treadmill calibration can cause the treadmill to start or stop. Never perform treadmill calibration while a person is on the treadmill. Calibration should be performed by Cardiac Science qualified biomedical technicians only.

WARNING! Patient injury.

The Quinton 9500 wall mount monitor can tilt up and down, but not from side-to-side. Never force the monitor to swivel or rotate. Forcing the monitor can cause it to break loose from the mount and fall.

WARNING! Patient safety.

When viewing multiple workstations using CareCenter MD Online, take care to keep patient screens in the same order or orientations, so that you do not confuse data from multiple patients.

Caution: Possible mis-diagnosis

Some pacer spikes may create a minor ringing distortion in the ECG waveform following the pacer spike, which may appear to be a second spike. This ringing is not confused with a QRS complex by the interpretive algorithm. To reduce the ringing effect, de-select one or more of the ECG filters.

Caution: Patient injury

To prevent injury from the treadmill starting unexpectedly or at the wrong speed, always have the patient straddle or stand on the side of the treadmill until the treadmill is running at the correct speed. Never start the treadmill with the patient on the treadmill.

Caution: Patient injury

To prevent injury from the treadmill stopping suddenly, always inform the patient before stopping the treadmill.

Caution: Incomplete or inaccurate data.

When using CareCenter MD Online, ensure text message boxes are positioned so the boxes not to overlap and obscure data.

Caution: Incomplete or inaccurate data.

Using or configuring features during acquisition may cause windows that obscure data or functionality. Do not access **File | Options...** during acquisition.

Interference

Caution: Electromagnetic interference

Electric or magnetic fields can affect the ECG device registration process. Ensure that there is no X-ray arrays or high performance transformers are near the device.

Caution: Electromagnetic interference.

Using multiple devices which are attached to the patient can cause the acquisition device to malfunction. If another device is attached to the patient watch the acquisition device closely for changes in the display. If changes occur in the display, do not connect additional devices and contact Cardiac Science Technical Support.

Caution: Electromagnetic interference.

This device can be affected by electromagnetic interference. If electromagnetic interference is observed, refer to the recommended separation distances in the EMC declaration tables.

Caution: Electromagnetic interference.

Bluetooth wireless technology data transmission may be impaired if large number of devices are active simultaneously.

Caution: Erroneous results.

The calculation of physiological parameters can be distorted when using a filter. Faulty calculations should be recognizable by a physician or a trained technician, confirm all diagnoses with a physician.

Caution: Data Transmission.

Electromagnetic interference can cause the QRS synchronization signal to be missing, which can effect the stress test. Verify the plausibility of the result. For example, the heart rate on the Tango should not be lower than the heart rate recorded by the CareCenter MD.

Damage and repair

Caution: Enclosure damage

Damage to the device enclosure can prevent effective isolation of the applied parts. Do not use any parts that appear damaged. Check the device for damage before using and reject any parts that have been damaged in shipping.

Caution: Void warranty

Assembly operations, extensions, re-adjustments, modifications, or repairs must be carried out by Cardiac Science-trained or Cardiac Science-authorized personnel only.

Caution: Cleaning and disinfection.

If any matter (gaseous, liquid, or solid matter) enters the acquisition device enclosure, you must clean the device and then have it inspected by Cardiac Science service personnel.

Caution: Cleaning and disinfection

If the device becomes dirty or contaminated with bodily fluids, clean with a moist cloth. If necessary, use an alcohol-containing disinfectant and ensure no liquid enters the device housing.

Caution: Cleaning and disinfection

To prevent damage to the device, never clean the device with sharp objects or aggressive cleaning agents/disinfectants. Clean with a moist cloth. If necessary, use an alcohol-containing disinfectant and ensure no liquid enters the device housing.

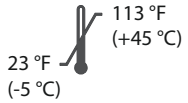
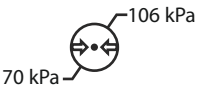
Caution: Acquisition device maintenance

While there are no parts that require maintenance on the acquisition devices, perform a visual inspection and ensure safe operation every two years.

Symbols and labels

Cardiac Science Corporation products display one or more of these symbols and warning labels for your protection.

Symbol	Description
	Attention: Consult accompanying documents
	Warning symbol
	Type CF equipment - contains an F-type isolated patient applied part and provides a degree of protection against electric shock higher than that for type BF equipment regarding allowable leakage currents
	Type CF equipment with defibrillation protection
	Protect from heat
	Fragile handle with care.
	Keep dry
	By prescription only

Symbol	Description
	Do not expose to temperatures below this limit (shipping and handling). For more information on environmental parameters see *Specifications* on page 27.
	Atmospheric pressure must be within these limits (shipping and handling). For more information on environmental parameters see *Specifications* on page 27.
	Humidity must be within these limits (shipping and handling). For more information on environmental parameters see *Specifications* on page 27.
	Interference may occur in the vicinity of equipment marked with this symbol
	Date of manufacture
	Manufactured for
	Use this battery/accumulator rating
	Battery terminal symbol
FCC ID: X8X-CCMD-BT	FCC ID number

Symbol	Description
	This product is listed by CSA International as certified
	Maintains a certified quality management system according to DIN EN ISO 13485:2003 and DIN EN ISO 9001:2000 as well as a certificated quality assurance system according to MDD 93 / 42 / EEC, Annex II.
SN or SN	Serial number
REF or REF	Orderable part number
LOT	Batch code
BLUETOOTH CLASS 1	Device corresponds to the *Bluetooth* class 1
	*Bluetooth* wireless technology enabled device

Cleaning and care

Patient cable

Connect the patient cable to the acquisition device according to the instructions for the device in the *Connecting the Acquisition Devices* quick steps. During the preparation for an acquisition, the system will prompt you to attach the leads to a patient.

Patient cable use

This cable is intended to be used for the hook-up of a patient to an electromedical device with the purpose of sensing electrocardiography signals from the human skin using appropriate disposable or reusable ECG electrodes. The application must be performed by a skilled medical professional. Use the patient cable only as it is intended.

WARNING! Electrical safety.

Mis-using the patient cable can cause shock. Never attempt to connect the patient cable directly to power. Connect the patient cable directly to the acquisition device and use the patient cable only as directed.

WARNING! Patient safety.

To prevent tripping, always ensure the patient belt allows freedom of movement. Use the belt loops to manage excess cable length. Before beginning the test, ensure there are no obstructions.

- Check the cable integrity before each use.

  In case of damage of any kind, do not use and do not attempt to repair cable. Consult your biomedical technician. If cable is found to be contaminated, clean it and disinfect it (see *Cleaning and disinfecting the patient cable*), before reusing the cable.

- Plug the connector into its receptacle and connect all patient lead wires to ECG electrodes suitable for your application. Make sure the electrodes and patient connectors are placed correctly following the on-screen instructions.
- Tape the patient lead wires to the skin if necessary to avoid movement artifacts. Pay attention to achieve a sensible and ergonomic cable routing
- If you experience disturbance, distortion or interruptions of the signal, stop the procedure and determine the source and, if possible, amend the problem before you continue.
- At the end of the procedure, gently disconnect the electrode connectors from the electrodes. The connector could still be latched, ensure the connector is unlatched before pulling on the connector.
- Store cable hanging in big loops.

  DO NOT coil the patient cable tightly. Avoid heat sources and direct sunlight.
- Cables are supplied non-sterile and are reusable. Clean and disinfect the patient cable before use. For cleaning and disinfection See *Cleaning and disinfecting the patient cable*.

Cleaning and disinfecting the patient cable

Caution: Cleaning and disinfection.

Never immerse or soak the patient cable.

Caution: Cleaning and disinfection.

Prolonged alcohol exposure can negatively affect the mechanical properties of the cable jacket.

Caution: Cleaning and disinfection.

Do not use N-propyl alcohol or sodium hypochlorite (bleach, Chlorox) for disinfection of the cables. Do not use any organic solvents to clean and disinfect the cable. Acetone, tolouol or other organic solvents will damage the cable jacket.

To clean the patient cable:

1. Disconnect the cable from the patient and the acquisition device.
2. Wipe the plastic parts with a cloth moistened in lukewarm water with alcohol-free neutral soap.

   Always wipe in the direction of the patient connectors. Proceed carefully so as not to damage the cable through excessive stretching, bending or kinking of the wires. Remove adhesive residues with the alcohols listed in this procedure only.
3. Remove the cleaning agent by wiping the cable with a cloth moistened in water.
4. To disinfect:
   a. Perform wipe disinfection using products with these substances as the active ingredients:
      - Ethyl or Isopropyl alcohol 70 - 80%
      - Glutaraldehyde 2% (pH 7.5 - 8) (e.g. Cidex®)
      - Quaternary ammonium compounds (e.g. Sanicloth HB wipes)
   b. Remove the disinfectant immediately after the recommended contact time by wiping the cable with a cloth moistened in water
5. Wipe or air dry before use.

Sterilizing the patient cable

Caution: Cleaning and disinfection.

The materials used in the patient cable are not suitable for autoclave or UV sterilization.

To avoid long-term damage of the cables, sterilize only when necessary as determined by the guidelines for your hospital. The cable can withstand standard EO (EtO) sterilization cycles (1 hour, < 57 °C, < 75% rel. humidity).

Ensure the correct aeration time has elapsed before using the cable.

Acquisition devices

The acquisition devices are described in the *CareCenter MD™ System Setup Guide*.

WARNING! Electric shock

The acquisition devices are not splash-proof. Protect the device from all sources of water and liquids. Do not use the device outdoors. If liquid spills into the device, immediately disconnect the patient and stop using the device. Once the device is dry, it must be cleaned, disinfected and tested. For more information contact Cardiac Science Technical Support.

Cleaning and disinfecting the acquisition devices

Clean and disinfect any acquisition device that becomes dirty or contaminated with bodily fluids.

Caution: Cleaning and disinfection

To prevent damage to the device, never clean the device with sharp objects or aggressive cleaning agents/disinfectants. Clean with a moist cloth. If necessary, use an alcohol-containing disinfectant and ensure no liquid enters the device housing.

To clean and disinfect the device:

1. Wipe the acquisition device with a cloth moistened in lukewarm water with alcohol-free neutral soap.
2. To disinfect:
   a. Perform wipe disinfection using products with these substances as the active ingredients:
      – Ethyl alcohol 70 - 80%
      – Glutaraldehyde 2% (pH 7.5 - 8) (e.g. Cidex®)
   b. Ensure no liquid enters the device housing.
   c. Remove the disinfectant immediately after the recommended contact time by wiping the cable with a cloth moistened in water.
3. Wipe or air dry before use.

Maintenance

Follow the procedures in this section to properly maintain the system

- Follow all cleaning and care procedures as described in this manual and the installation instructions.

Before use

Before using the system, components, or associated equipment:

- Inspect the system for damage. Look for:
  - Frayed or damaged cables
  - Dents, bulges or cracks in the housing
  - Loose or improper connectors
  - Faulty or missing hardware
  - Other signs of wear
- Perform a safety check of the system:
  - Ensure the system and associated equipment does not present a tripping hazard.
  - Ensure the system and associated equipment will not fall on a patient or operator.
  - Provide space around the equipment so that a patient can mount and dismount the exercise equipment safely.
  - Ensure cables do not interfere with any moving parts.
  - Ensure the environment is well-ventilated and free of flammable gases.
- Ensure the system is clean and ready for use.

Periodically

- Perform backups of patient and test data on a regular schedule. For more information on backing up the system see the *CareCenter MD™ User's Guide*.
- Periodically run virus checks when CareCenter MD is not in operation.

Specifications

Safety Standards

- ISO 10993-1 - Biological evaluation of medical devices
- EN 60601-1 - Medical Electrical Equipment – Part 1: General requirements for safety
- EN 60601-1-1 - Medical Electrical Equipment – Part 1: General requirements for safety. Collateral Standard: Safety requirements for medical electrical systems
- EN 60601-2-25 - Medical Electrical Equipment Part 2-25: Particular requirements for the safety of electrocardiographs
- EN 60601-1-4 - Medical Electrical Equipment – Part 1-4: General requirements for safety. Collateral Standard: Programmable electrical medical systems
- AAMI/ANSI/IEC 60601-1-2 - Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- FCC Title 47 Part 2 including section 2.1093 - Radio frequency radiation exposure evaluation: portable devices
- IEC 60601-2-51 - Medical electrical equipment -- part 2-51: Particular requirements for the safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs
- IEC/EN 60601-2-27 - Medical electrical equipment -- Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
- AAMI EC53/(R) - ECG cables and leadwires
- AAMI/ANSI EC-57 - Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms

General Requirements

	USB	Bluetooth
Normal use	• resting ECGs • stress test ECGs • emergency ECGs	• resting ECGs • stress test ECGs • emergency ECGs

Regulatory standards

Standards	USB	Bluetooth
Safety	• EN 60601-1 • EN 60601-1-1 • EN 60601-2-25 • Guide 93/94/ EEC	• EN 60601-1 • EN 60601-2-25 • Guide 93/94 /EEC
Protection	• EN 60529	• EN 60529
Performance	• EN 60601-2-51	• EN 60601-2-51

Electromagnetic Compatibility

- EN 60601-1-2—Electromagnetic compatibility - requirements and tests
- EN 55011/CISPR 11—Radio disturbance characteristics - limits and methods of measurement
- EN 61000-4 -2—Electrostatic discharge immunity test
- EN 61000-4 -3—Radiated RF electromagnetic field immunity test
- EN 61000-4 -4—Electrical fast transients/bursts immunity test
- EN 61000-4 -5—Surge immunity test

- EN 61000-4 -6—Immunity to conducted disturbances, induced by radio-frequency fields
- EN 61000-4 -8—Power frequency magnetic field immunity test

Classification

	USB	Bluetooth
Safety		
Risk class	U.S. FDA Class II IIa according to guideline 93/42/EEC, annex IX	U.S. FDA Class II IIa according to guideline 93/42/EEC, annex IX
Class	Intended for power supply by USB 2.0 port Connection to Class I or with internal supply equipment according to EN 60601-1 clause 5.1 and annex BBB situation 1c	--
Protection Class	Intended for power supply by USB 2.0 port. Connection to class I or with internal supply equipment according to EN-60601-1	Internally powered according to EN 60601-1:2007 clause 6.2
Type	CF according to EN 60601-1	CF according to EN 60601-1
Operation Mode	Continuous according to EN 60601-1:2007 clause 5.6	Continuous according to EN 60601-1:2007 clause 6.6
Degree of protection	IP20 according to EN 60529	IP20 according to EN 60529
Electromagnetic compatibility		
Group	1 according to CISPR 11	1 according to CISPR 11
Class	B according to CISPR 11	B according to CISPR 11

	USB	Bluetooth
Environmental Conditions		
Operation	• Temperature range +5 °C through +40 °C • Relative humidity 5% through 85% • Air pressure 70 kPa through 106 kPa	• Temperature range +5 °C through +40 °C • Relative humidity 5% through 85% • Air pressure 70 kPa through 106 kPa
Transportation	• Temperature range -25 °C through +70 °C • Relative humidity <95% at 40 °C • Air pressure >70 kPa	• Temperature range -25 °C through +70 °C • Relative humidity <95% at 40 °C • Air pressure >70 kPa
Storage	• Temperature range -5 °C through +45 °C • Relative humidity 5% through 95% • Air pressure 70 kPa through 106 kPa	• Temperature range -5 °C through +45 °C • Relative humidity 5% through 95% • Air pressure 70 kPa through 106 kPa

Mechanical

	USB	Bluetooth
Enclosure		
Enclosure	Isolated plastic enclosure	Insulated plastic enclosure with battery case for 2 cells size AA. Battery case cover manually removable with a tool
	15-pin D-Sub socket with UNC 4-40 nuts for patient cable connection	15-pin D-Sub socket with nuts UNC 4-40 for patient cable connection
	Fixed USB cable with USB-A plug	--
Dimensions	95 x 64 x 28 mm^3 without USB cable	110 x 65 x 28 mm^3
Mass	<100 g	160 g (with batteries)
Controls	--	ON/OFF
Indicators	--	• On • Online • Low Battery
Cable		
USB Cable	• Length — 5m • Tension force — 40 N for 1 min according to USB 2.0 • Cable type — USB-A	--

	USB	Bluetooth
Patient Cable	• Pin assignment according to IEC 62D(CO)6 annex F.2.1 • Color code according to EN 60601-2-51 table 101 Code 1 or Code 2 • Lead capacitance of patient cable ≤ 2	• Pin assignment according to IEC 62D(CO)6 annex F.2.1 • Color code according to EN 60601-2-51 table 101 Code 1 or Code 2 • Lead capacitance of patient cable ≤ 2

Electrical

	USB	Bluetooth
Performance		
Input voltage range (patient cable)	-316 mV through +316 mV	-316 mV through +316 mV
Common mode rejection	≥ 120 dB	≥ 120 dB
Input impedance	≥ 50 MΩ	≥ 50 MΩ
Signal band width -3dB	0 Hz through 150 Hz after low pass filter	0 Hz through 150 Hz after low pass filter
Sample rate	8000 Hz	8000 Hz
Resolution while acquisition	18 Bit, 2.576 µV / LSB, 388 LSB / mV	18 Bit, 2.576 µV / LSB, 388 LSB / mV
Noise level	≤ 20 µV p-p in frequency range 0.05 Hz through 150 Hz	≤ 20 µV p-p in frequency range 0.05 Hz through 150 Hz

	USB	Bluetooth
Pacemaker detection threshold	Amplitude ≥ 2 mV, Duration ≥ 200 µs, Edge times ≤ 100 µs	Amplitude ≥ 2 mV Duration ≥ 200 µs Edge times ≤ 100 µs
Pacemaker detection method	Digital	Digital
Defibrillation protection	Requires patient cable with 10 kΩ resistors	Requires patient cable with 10 kΩ resistors
RF-surgery tool protection	Protection against damage of device ECG acquisition during application of RF surgery tools is not recommended	Protection against damage of device ECG acquisition during application of RF surgery tools is not recommended
Impedance measurement	Patient auxiliary current AC (Sinus) 15.625 Hz 20 nA p-p	Patient auxiliary current AC (Sinus) 15.625 Hz 20 nA p-p
Electrode monitoring	Patient auxiliary current DC 10 nA	Patient auxiliary current DC 10 nA
QRS trigger	--	ISM 433.92 MHz, FSK modulation Transmit power ≤ 10 mW Jitter ≤ 10 ms
Safety		
Patient auxiliary current	≤ 100nA	≤ 100nA
Patient leakage current	≤ 10 µA NC, ≤ 50 µA SFC according to EN 60601-1 clause 19.3 table IV and ANSI/AAMI ES1 clauses 4.4 and 4.5	≤ 10 µA NC, ≤ 50 µA SFC according to EN 60601-1:2007 clause 8.7.3 b) and ANSI/AAMI ES1 clauses 4.4 and 4.5

	USB	Bluetooth
Touch current	--	≤ 100 µA NC, ≤ 500 µA SFC according to EN 60601-1:2007 clause 8.7.3 c) and ANSI/AAMI ES1 clause 4.3
Enclosure leakage current	≤ 500 µA NC, ≤ 1000 µA SFC according to EN 60601-1 clause 19.3 table IV and ANSI/AAMI ES1 clause 4.3	--
Earth leakage current	≤ 500 µA NC, ≤ 1000 µA SFC according to EN 60601-1 clause 19.3 table IV and ANSI/AAMI ES1 clause 4.6	--
Applied part	Reinforced insulation according to EN 60601-1 clauses 17 a) 4), 20.1 A-k, 20.2 B-d	--
Dielectric strength	4000 V RMS / 1 min according to EN 60601-2-25 clause 20.3	≥ 4000 V rms / 1 min according to EN 60601-2-25 clause 20.3
ECG recovery time after defibrillation	• ECG is available 5 s after defibrillation according to EN 60601-2-25 clauses 51.101.1 and 51.101.2 • ECG is available 10 s after defibrillation according to EN 60601-2-25 clause 51.102	• ECG is available 5 s after a defibrillation according to EN 60601-2-25 clause 51.101.1 and 51.101.2 • ECG is available 10 s after a defibrillation according to EN 60601-2-25 clause 51.102

	USB	Bluetooth
Power supply		
	• Power supply from USB 2.0 Port • Current consumption in modes ECG acquisition and electrode monitoring ≤ 160 mA • Current consumption in mode Ready ≤ 50 mA • Current consumption in mode Suspend ≤ 2.5 mA	• 2 cells size AA (R6), NiMH capacity ≥ 2500 mAh, external charge, or alkaline primary cells 1.5 V • Current consumption 130 mA (fully charged) through 180 mA (empty) while signal acquisition and transmission and supply from NiMH batteries • Operation period at continuous data transmission ≥ 10 h at supply from fully charged NiMH batteries 2500 mAh
Electrical rating	5V	5V

EMC declaration tables

The CareCenter MD acquisition devices are compliant with IEC 60601-1-2 EMC immunity requirements.

This section lists the Electromagnetic compatibility tables.

WARNING! Electromagnetic interference.

Position the acquisition device away from other electrical or electronic equipment if possible. The presence of strong EMI fields, or generated by RF noise on the line power, or by electronic, surgical, or diathermy instruments in close proximity to the acquisition device may cause trace noise or input overload conditions.

If used with, or around, other electrical or electronic equipment, always carefully monitor initial readings to verify normal operation.

CareCenter MD USB

CareCenter MD USB is intended for the use in an electromagnetic environment defined below.

Table 1: Electromagnetic emissions

Emission test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group1	CareCenter MD USB uses electromagnetic energy only for internal purposes. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CareCenter MD USB is suitable for use in all establishments

Table 2: Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic compliance guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for input/ output lines	Mains power quality should be typical of a commercial or hospital environment.
Conducted disturbances, induced by radio frequency fields IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} [c] 150 kHz through 80 MHz 3 V/m [c] 80 MHz through 2.5 GHz	3 V_{rms} for input/ output lines 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CareCenter MD USB, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.17 * P^{1/2}$ $d = 1.17 * P^{1/2}$ for 80 MHz through 800 MHz $d = 2.33 * P^{1/2}$ for 800 MHz through 2.5 GHz d: distance in m P: transmitted power in W 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: 

Table 2: Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic compliance guidance
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be typical of a commercial or hospital environment.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.

Note 2: 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 can-not 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 CareCenter MD USB is used exceeds the applicable RF compliance level above, then the CareCenter MD USB should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CareCenter MD USB.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

[c] Amplitude modulated at 80% with a modulation frequency of 10 Hz per EN 60601-2-25

Refer to Table 3 for recommended separation distances between the CareCenter MD USB and portable and mobile RF communications equipment.

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

Table 3: Recommended Separation Distances

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz through 80 MHz $d = 1.17 * P^{1/2}$	80 MHz through 800 MHz $d = 1.17 * P^{1/2}$	800 MHz through 2.5 GHz $d = 2.33 * P^{1/2}$
0.01	0.12	0.12	0.24
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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 W according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CareCenter MD BT

CareCenter MD BT is intended for the use in an electromagnetic environment defined below.

Table 4: Electromagnetic emissions

Emission test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group1	CareCenter MD BT uses electromagnetic energy only for internal purposes except for the transmission of the QRS trigger pulse in the ISM band 915 MHz. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CareCenter MD BT is suitable for use in all establishments

Table 5: Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic compliance guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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%.
Conducted disturbances, induced by radio frequency fields IEC 61000-4-6	3 V_{rms} [c] 150 kHz through 80 MHz	3 V_{rms} for input/ output lines	Portable and mobile RF communications equipment should be used no closer to any part of the CareCenter MD BT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.17 * P^{1/2}$ $d = 1.17 * P^{1/2}$ for 80 MHz through 800 MHz
Radiated RF IEC 61000-4-3	3 V/m [c] 80 MHz through 2.5 GHz	3 V/m	$d = 2.33 * P^{1/2}$ for 800 MHz through 2.5 GHz d: distance in m P: transmitted power in W 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: 

Table 5: Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic compliance guidance
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be typical of a commercial or hospital environment.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.

Note 2: 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 can-not 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 CareCenter MD BT is used exceeds the applicable RF compliance level above, then the CareCenter MD BT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CareCenter MD BT.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

[c] Amplitude modulated at 80% with a modulation frequency of 10 Hz per EN 60601-2-25

Refer to Table 6 for recommended separation distances between the CareCenter MD BT and portable and mobile RF communications equipment.

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

Table 6: Recommended Separation Distances

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz through 80 MHz $d = 1{,}17 * P^{1/2}$	80 MHz through 800 MHz $d = 1{,}17 * P^{1/2}$	800 MHz through 2.5 GHz $d = 2{,}33 * P^{1/2}$
0.01	0.12	0.12	0.24
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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 W according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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