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Descriptive Information

What Is CardiacConnect™ Cardiac Rehabilitation System model 10300?

The ROMTech CardiacConnect™ Cardiac Rehabilitation System (CardiacConnect) is a cardiac rehabilitation and monitoring system in one. It helps keep an eye on patients while they're exercising for their heart health. It's used during planned workout sessions to make sure you're exercising at the right intensity and for the right amount of time.

What is included with CardiacConnect?

CardiacConnect™ consists of:

- (1) Rehabilitation device with integrated interactive tablet (telehealth portal):
  - (1) Electronic copies of CardiacConnect and all auxiliary device IFUs (saved in tablet for patient access)
- (1) Installation materials
  - (1) Device distance scale
  - (4) Non-slip pads
  - (1) Quick Start Guide
- (1) Charging and storage station (CSS) for the following auxiliary devices:
  - (1) Blood Pressure (BP) device
  - (1) Electrocardiogram (ECG) device
  - (1) Pulse Oximeter (SpO2) device

What you need at home:

- (1) Wall – tall enough to have back of a stable chair placed against it
- (1) Clean, level, unobstructed floor space in front of wall (about 8 feet long and 3 feet wide)
- (1) Stable Chair - 4-legged with fixed back support (the back of chair will need to rest against the wall)
- (1) Table – (about 1 foot wide by 1 foot deep)
- (1) Power plug in – 120-VAC receptacle within 10 ft of device (this is typical in most homes)

Who is clinically eligible to use CardiacConnect?

If you receive a prescription for Cardiac Rehabilitation (CR) from your doctor, you are eligible to use CardiacConnect™.

Intended Use/Indications for Use:

The CardiacConnect™ is used during the prescribed CR of patients that have undergone treatment for cardiac conditions, and follow-on prescribed post-rehabilitation sessions. During this in-home multi-session rehabilitation treatment, the patient performs exercise sessions during which session data including Resistance Level, Revolutions Per Minute (RPM), ECG, BP and SpO2 are monitored remotely by a qualified specialist who assesses the patient's response and adjusts the session parameters; accordingly, and also instructs the patient per the educational guidance in the treatment plan.

Limitations of Use (Contraindications)

CardiacConnect™ shall not be used outside of physician prescribed sessions. It is contraindicated for use with the following groups:

- Patients who have not qualified for cardiac rehabilitation per American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) guidelines.
- Patients who have been diagnosed with serious or life-threatening arrhythmias and /or require hospitalization.
- Patients who require inpatient monitoring using a life-saving device.
- Heart transplant patients
- Patients with Left Ventricular Assist Devices (LVAD)
- Patients who use Mobile Cardiac Outpatient Telemetry (MCOT), Holter devices or other remote monitoring for telemetry
- Patients with a confirmed allergy to silicone, hydrogel, plastics, or rubber

Warnings

WARNING do not use any other accessories (BP, SpO2 or ECG device) with CardiacConnect™. If used, they could display inaccurate readings about your health.

WARNING do not use other medical equipment or devices with wireless capability (cell phone, portable computer etc.) during your cardiac rehabilitation session unless instructed by your CRS. They may affect the performance of the CardiacConnect™ device.

WARNING Do not remove the tablet when you are in an active rehabilitation session to avoid a potential electrical shock injury. Always inspect accessory connectors and cables for signs of damage in order to avoid a potential electrical shock injury.

WARNING Do not plug CardiacConnect into a power strip to avoid a potential electrical shock injury.

WARNING Do not modify CardiacConnect™ power cable or use in any other manner than as suggested for only powering the device as it may cause strangulation due to its length.

WARNING Do not modify CardiacConnect™ or accessories to avoid a potential electrical shock injury.

⚠ WARNING!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of ROMTech CardiacConnect™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This product generates, uses, and can radiate radio frequency energy, which may cause interference to other equipment. If in doubt about possible interference to other equipment, please contact your distributor or ROMTech for support.

⚠ WARNING!

Use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the ROMTech CardiacConnect™ as replacement parts for internal components, may result in increased emissions or decreased immunity of the ROMTech CardiacConnect™.

⚠ WARNING!

The ROMTech CardiacConnect™ should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the ROMTech CardiacConnect™ should be observed to verify normal operation in the configuration in which it will be used.

Please refer to the tables included later in this section for more information regarding electromagnetic compatibility.

⚠ WARNING!

Do not remove batteries from the ROMTech CardiacConnect™. Doing so could result in fire or electrical shock. The batteries are intended to be replaced by trained service personnel only.

⚠ CALIFORNIA PROPOSITION 65 WARNING!

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

For more information: www.P65Warnings.ca.gov

Precautions

- CAUTION Do not place CardiacConnect™ ECG device on top of Pacemaker or defibrillator. If this happens, it could lead to a possible delay in transmission of your cardiac accessories to your clinical team during session.
- CAUTION do not place the ECG device on excessive skin or hair to avoid inaccurate results.
- CAUTION do not excessively bend or twist the ECG device as the device may -break and limit your ability to complete session.
- CAUTION Do not place the BP device cuff over a wound or inflamed area or on any arm with IV access or shunt to avoid further irritation to skin and tissue surrounding.
- CAUTION Do not place the BP device cuff on the arm on the side of a mastectomy due to risk of swelling or lymphedema to affected arm.
- CAUTION If your arm is smaller than 8.6” or larger than 16.5”, alert your CRS as a different sized BP device cuff may be needed for accurate results.
- CAUTION, if you have small and/or thin fingers, alert your CRS as a different sized SpO2 device sensor may be needed for accurate results.
- CAUTION Do not move excessively while measurements are being taken, it could cause inaccurate results.

- CAUTION Rehabilitation outside approved range, or with extreme resistance, or using/storing the device in extreme heat (above 104degrees F) can cause the device to abruptly shut off.
- CAUTION Do not move CardiacConnect™ once it is set up in your home, or outside supervised rehabilitation sessions or you may experience bodily injury or damage the medical device.
- CAUTION Do not use the accessories while they are charging, or CardiacConnect™ may not work properly.
- CAUTION turn off overhead ceiling fans during your sessions as they may cause clothing vibrations which lead to device interference and inaccurate results.

How will Cardiac Rehabilitation benefit me?

Rehab programs can be useful after leaving the hospital. They let you exercise with a group and give you special support to make healthy changes in your life. Usually, a CR program lasts for 12-15 weeks with 36 sessions, but your doctor might adjust it based on your health.

Here's what happens during rehab:

Doctors check your health and figure out what you need.

- You will exercise on machines like treadmills or bikes.
- A nurse keeps an eye on you for any changes in how you feel.
- You will follow a safe exercise plan that helps you get stronger.
- As you get better, you can do more intense exercises.
- If your doctor says it's okay, you might start strength training.
- They monitor your heart rate, blood pressure, oxygen levels, and ECG.

After finishing the program, you might feel a lot better. The doctor may also prescribe additional monitored sessions to help you transition from rehab to lifestyle-based healthy habits. It's important to keep up these healthy habits in your everyday life. Rehab can help you get back to an active life, lower the chance of more heart problems, and improve your overall quality of life.

How else will a rehab program help me?

- You might attend classes to quit smoking.
- A nutritionist can help you eat healthier.
- Your fitness level will improve.
- If needed, they'll help you lose weight.
- You'll learn ways to relax and manage stress.

How will rehabilitation with CardiacConnect benefit me?

Using CardiacConnect™ for rehab lets you do your CR right at home. Your sessions will be "virtual," which means a Cardiac Rehabilitation Specialist (CRS) or another trained technician will guide you through setting up the device, coach you during exercises, check on your health, adjust device settings, and keep an eye on your BP, SpO2, and ECG during each session, and refer to other session data collected as needed. You'll talk to the CRS through a tablet screen attached to the rehabilitation device. They'll communicate with you in real time, and you'll do the same. If something medical happens during

a session, a visual alert will be sent to your CRS and he/she will get in touch with a ROM Tech physician. Using CardiacConnect™ for rehab meets AACVPR guidelines, the standard of care in the U.S. This means the exercises you do at home with CardiacConnect™ are the same as the ones you'd do at a CR center. You will also receive the same health education that you would receive in a rehabilitation center. Your CRS will review your medical history and help you learn more about cardiac risk factors, the importance of eating a healthy diet and taking medications as prescribed. He/she will also teach you relaxation and stress management techniques.

How is my physician part of my cardiac rehabilitation through CardiacConnect?

After your cardiac event, your physician prescribed CR. ROMTech received your prescription and after the CRS confirms you are healthy enough to receive CR at home, ROMTech will charge the services back to your insurance provider. If you are not healthy enough to receive CR at home, you may still be eligible to receive services at a local facility, but you will need to check with your local physician.

Your CRS will design an individualized treatment plan for you using the AACVPR guidelines. This prescription is reviewed and approved by a ROMTech physician before your treatment begins. During your treatment, progress updates are sent to your referring physician. At the end of your CR, the CRS will conduct a discharge assessment session with you and submit a final progress report to your referring physician for follow-up and review with you.

What can I expect during each session?

Your insurance has approved for you to get CR services. Even if you're far from a rehab center or just prefer doing it at home, your doctor has set you up with CardiacConnect™ for rehab. Most sessions take about an hour, and you can do them in the comfort of your own home.

Here's what will happen: You'll use the CardiacConnect™ rehabilitation device for aerobic exercises. You'll pedal with increasing resistance (set by your CRS), making your heart rate go up slowly. While you exercise, you can chat with your CRS. If you ever find it hard to talk, they'll lower the resistance. Either of you can stop the session at any time with a button.

Throughout the rehabilitation session, a CRS will keep track of your blood pressure, heart rhythm and oxygen levels. If any of your vitals are unexpected, the CRS will guide you through relaxing and breathing exercises and then check it again. If they stay too high or your heart rhythms become irregular, a physician will be alerted.

Depending on your treatment plan your CRS may also guide you via the CardiacConnect™ portal in meditation and relaxation exercises.

You will also receive plan specific health education through the CardiacConnect™ portal.

After each session, you'll cool down and stretch following CRS guidance. They'll also remind you about your next appointment.

Operating Information

Initial Set Up Instructions

The CardiacConnect™ is delivered to your home and set up by a ROM Technologies Inc. trained technician:

A. You will need to provide a stable chair from your home and place its back against a wall, with the front toward the device.
B. The trained technician will place the CardiacConnect™ so that your legs fully stretch when you use the pedals.
C. The trained technician connects the CardiacConnect™ and CSS to an electrical outlet.
D. The trained technician will turn on the interactive tablet.
E. The trained technician will connect the device to the internet.
F. The trained technician will download your individualized training plan.
G. The trained technician will instruct you on the login process, explain the functionality of the wearable BP, SpO2 & ECG devices, and their connection steps, and show you where to access the auxiliary device's Instructions for Use (IFU).
H. At the end of the practice session the trained technician will instruct you on the logout process, removal of the auxiliaries and their proper respective connection in the CSS so they are ready next session.
I. You should also review each auxiliary device's IFU detailed instructions to familiarize yourself with device operation, cleaning protocol, charging and storage requirements.

Important things to confirm before your session:

- The CardiacConnect™ device is plugged into an electrical outlet and powered "On".
- The ECG device is clean and dry.
- You have a strong WIFI connection.
- The SpO2, ECG and BP devices are fully charged.
- Any medications you have taken that day.

Session Operation Instructions

A. Put on the ECG device per the instructions in the device IFU.
B. Put on the BP device per the instructions in the device IFU.
C. Put on the SpO2 monitor per the instructions in the device IFU.
D. Log on to the CardiacConnect™ device.
E. Sit in chair looking at the portal screen and wait for the CRS to greet you.
F. Follow the CRS' instructions to initialize the auxiliary devices to ensure that they a reading your vitals correctly.
G. Follow the CRS' instructions to start your session.
H. If at any time you need to pause the session, press the stop button (shaped like a stop sign) on the lower right-hand corner of the tablet touch screen.
I. At the conclusion of your session, carefully remove the ECG device and clean it then store the device per the instructions in the IFU. Do not discard any components of the ECG device unless instructed on the IFU.

J. At the conclusion of the session, carefully remove the BP device and clean it then store it per the instructions in the IFU. Do not discard the BP device.
K. At the conclusion of the session, carefully remove the SpO2 device and clean it then store it per the instructions in the IFU. Do not discard the SpO2 device.
L. At the conclusion of your session, log out of the session, but do not turn off the CardiacConnect™ interactive portal, the green power button should remain lighted.
M. If at any time you need to stop the session, press the protruding red button located at the bottom of the tablet screen.

Cleaning instructions

The CardiacConnect™ device was thoroughly cleaned before it was brought into your home. However, if you spill liquid on the interactive portal or rehabilitation device, you may clean the area with a dry, soft cloth or a moistened and well wrung out cloth. For detailed instructions on how to clean the auxiliary devices, refer to their respective IFU.

Storage and Maintenance

Do not move your CardiacConnect™ rehabilitation device after it has been set up by the technician. It should be set up in an area of your home where you will not trip or fall, on stable, clean flooring and at least 10 meters (32 feet) away from microwave oven. You do not need to perform any maintenance on the device. Store the device and accessories in their original packaging/case or lightly coiled (cables) away from excessive cold, light, heat and moisture.

Operational Requirements

Hardware and Software requirements

System Requirements

CardiacConnect™ is designed to operate within a temperature range of +5°C - +40°C and a relative humidity range of 15% - 90% and atmospheric pressure range of 700 hPa to 1060 hPa.

Electromagnetic Emissions Compliance

The ROMTech CardiacConnect™ has been tested and found to comply with the limits for medical devices to IEC 60601-1-2 Edition 3.0:2007 and IEC 60601-1-2 Edition 4.0:2014 standards. These limits are designed to provide reasonable protection against harmful interference in a typical installation.

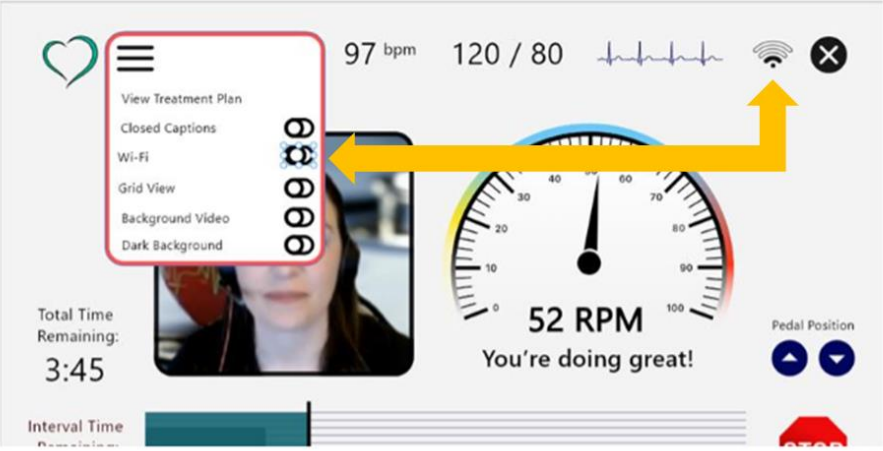
The device performance may be affected by heavy electrical equipment or other sources of electromagnetic interference.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Portable RF communications equipment can affect medical electrical equipment.

Troubleshooting

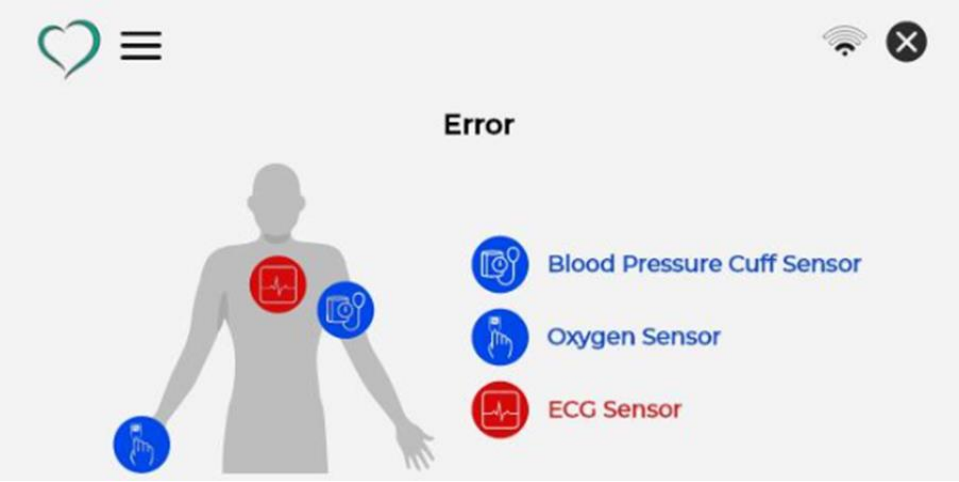
Issue: Weak Cellular or Wi-Fi Internet Connection



Troubleshooting Steps - When signal strength is weak:

A. Click Menu Icon.
B. Slide Wi-Fi toggle to switch between Wi-Fi and Cellular as needed.

Issue: Auxiliary Device Connection



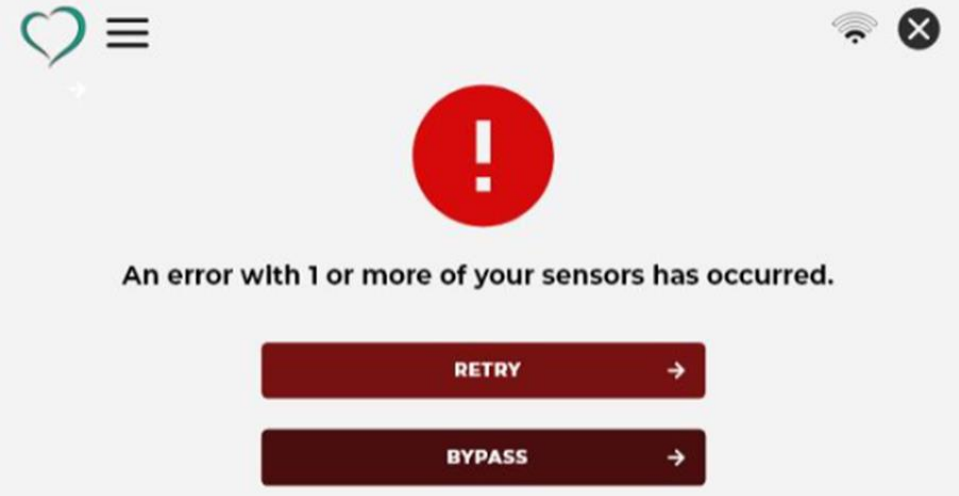
Troubleshooting Steps - When a device will not connect:

A. Make sure the device is charged.

B. Make sure the device is powered "On" as the device can go to "Sleep" within 30 seconds if connection has not been established.

C. Refer to device IFU for detailed instructions.

Issue: Auxiliary Device Loses Connection



Troubleshooting Steps - When a device loses connection:

A. Make sure the device is charged.

B. Reboot the device.

C. Refer to device IFU for detailed instructions.

Symbol Glossary

Symbols for Warnings, Precautionary Measures and Notes
The following conversations are used in this manual:

WARNING!
This symbol advises the user of serious danger for the patient and the user.

CAUTION!
This symbol informs the user that particular care is required for safe and efficient operation of the system.

IMPORTANT NOTE
This symbol provides the user with useful or additional information.

INFORMATION
This symbol provides the manufacturer name and address.

INFORMATION
This symbol provides customer support information.

Symbols for Labels

The following conventions can be found in the CardiacConnect™ Rehab System.

INFORMATION
This symbol indicates date of manufacture.

INFORMATION
This symbol indicates the catalogue number.

INFORMATION
This symbol indicates the serial number.

INFORMATION
This symbol indicates a Type BF Applied Part.

INFORMATION
This symbol indicates consult instructions for use.

INFORMATION
This symbol indicates Class II equipment.

INFORMATION
This symbol indicates AC power from building.

INFORMATION
This symbol indicates separate collection for safe disposal.

INFORMATION
This symbol indicates wireless transmission.

INFORMATION
This symbol indicates the system is protected against condensation.

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info@romtech.com

Electrical Rating

The rating tag for the CardiacConnect™ is set at 108V – 132 VAC, 2.3A - 1.9A, 50/60Hz. 250 W.

The CardiacConnect™ runs on three main wireless protocols to envision its essential performance:

Wireless technology	Transmitter / Receiver Bandwidth	Modulation Scheme	Data rates	Power Level
BLE v5.2	2402 to 2480 MHz	GFSK	2 Mbps	-20 dBm to 4 dBm
Wi-Fi	2.4 GHz + 5.180 -5.240 GHz 5.260- 5.320 GHz 5.500- 5.720 GHz 5.745- 5.825 GHz	1024-QAM	450 Mbps	20 dBm
Cellular	4G LTE FDD - B1(2100),B2(1900),B3(1800),B4(AWS),B5(850),B7(2600),B8(900),B12(700),B13(700),B14(700),B20(800),B25(1900),B26(850),B28(700),B29(700),B66(AWS-3),B71(600) 4G LTE TDD- B41(2500),B48(3600) 5G Sub6 FDD- N2(1900),N5(850),N25(1900),N66(AWS-3),N71(600) 5G Sub6 TDD- N41(2500),N77(3700),N78(3500)	FDD, TDD	150 Mbps - Download 50 Mbps - Upload	30 dBm

The fuses used in the CardiacConnect™ have the following ratings:

Item	Ref Des	Fuse Mfg.	Fuse Mfg. Part Number	Description	Related Boards
1	F1	Bel	0ZCF0185FF2C	Polymeric PTC Resettable Fuse 33V 1.85A Ih Surface Mount 2920 (7351 Metric), Concave	10145-200 rev 2
2	F1	Bel	0ZCF0185FF2C	Polymeric PTC Resettable Fuse 33V 1.85A Ih Surface Mount 2920 (7351 Metric), Concave	15336-200 rev 2
3	R432	Murata	NCP15XH103F03RC	NTC Thermistor 10k 0402 (1005 Metric)	15749-200 rev 7
4	R433	Murata	NCP15XH103F03RC	NTC Thermistor 10k 0402 (1005 Metric)	15749-200 rev 7
5		Murata Electronics	NXFT15XH103FA2B100	Motor Thermistor	10980 Rev 5

Standards and Compliances

CardiacConnect™ device and accessories complies with the follow standards:

IEC 60601-1 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 - Electromagnetic Compatibility (EMC) Testing for Medical Devices
IEC 60601-2-27 - Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 60601-1-11 Medical electrical equipment General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-8 - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 62304 Medical Device Software Lifecycle Processes
IEC 62366-1 Application of usability engineering to medical devices
ISO 14971 Medical devices — Application of risk management to medical devices
ISO 24971 Medical devices Guidance on the application of ISO 14971
ISO 80601-2-30 - Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 80601-2-61 - Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Electromagnetic Emissions Compliance and Instructions

The ROMTech CardiacConnect™ has been tested and found to comply with the limits for medical devices to IEC 60601-1-2 Edition 3.0:2007 and IEC 60601-1-2 Edition 4.0:2014 standards. These limits are designed to provide reasonable protection against harmful interference in a typical installation.

The device performance may be affected by heavy electrical equipment or other sources of electromagnetic interference.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Portable RF communications equipment can affect medical electrical equipment.

IEC 60601-1-2 Edition 4.0: 2014 Requirements

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ROMTech CardiacConnect™ is intended for use in the electromagnetic environment specified below. The customer or the user of the ROMTech CardiacConnect™ should assure that it is used in such an environment.		
Emissions	**Test Compliance**	**Electromagnetic Environment Guidance**
RF emissions CISPR 11	Group 1, Class B	The ROMTech CardiacConnect™ 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 ROMTech CardiacConnect Rehab System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
The ROMTech CardiacConnect™ is intended for use in the electromagnetic environment specified below. The customer or the user of the ROMTech CardiacConnect™ should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±4 kV air ±8 kV Contact	±4 kV air ±8 kV Contact	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 100 kHz repetition frequency	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV line to line ±0.5kV line to line	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0%, ½ cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0%, 1 cycle. 70%, 30 cycles 0%, 300 cycles	Not applicable	Not applicable

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
The ROMTech CardiacConnect™ is intended for use in the electromagnetic environment specified below. The customer or the user of the ROMTech CardiacConnect™ should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8:2009	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
IEC 61000-4-39:2017 Radiated Fields in Close Proximity	30 kHz, CW, 8 A/m 134.2 kHz, 2.1 kHz Pulse Modulation, 65 A/m 13.56 MHz, 50 kHz Pulse Modulation, 7.5 A/m		

Guidance and Manufacturers Declaration – Electromagnetic Immunity				
IEC 60601-1-2:2014 + AMD 1:2020 Clause 8.10 Immunity to Proximity Fields from RF wireless communications Equipment.				
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**IMMUNITY TEST LEVEL(V/m)**
385	380 to 390	TETRA 400	Pulse Modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ±5 kHz deviation, 1 kHz sine	28
710, 745, 780	704 to 787	LTE Band 13,17	Pulse modulation 217	9
810 ,870 ,930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850 , LTE Band 5	Pulse modulation 18 Hz	28
1720, 1845, 1970	1700 to 1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25 ; UMTS	Pulse modulation 217 Hz	28
2450	2400 to 2570	Bluetooth, WLAN. 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240, 5500, 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
The ROMTech CardiacConnect™ is intended for use in the electromagnetic environment specified below. The customer or the user of the ROMTech CardiacConnect™ should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6	3 Vrms, 0.15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Not applicable Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = [3,5/V1]\sqrt{P}$ (80 to 800 MHz) $d = [3,5/E1]\sqrt{P}$ (800 MHz to 2.5 GHz) $d = [7/E1]\sqrt{P}$ 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 meters (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:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m 80 MHz to 2,7 GHz, 80% AM at 1 kHz	

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
The ROMTech CardiacConnect™ is intended for use in the electromagnetic environment specified below. The customer or the user of the ROMTech CardiacConnect™ should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
NOTE 1 At 80 MHz and 800 MHz, 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 strength 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 system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as orientating or relocating the system. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and ROMTech CardiacConnect			
The ROMTech ROMTech CardiacConnect™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the ROMTech CardiacConnect™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ROMTech CardiacConnect as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output power of the transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 3.5\sqrt{P}$	**80MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power ration of the transmitter in watts (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.			

FCC Compliant statement

This medical device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Important Information

To maintain compliance with FCC regulations, please adhere to the following guidelines:

- **Proper Usage**: Use this medical device only in accordance with the instructions provided in this user guide.
- **Interference**: This device may cause interference to other electronic devices. If interference occurs, try relocating the affected devices or contact our customer support for assistance.
- **Modifications**: Modifications to this device not expressly approved by the manufacturer may void FCC compliance and could result in improper operation.
- **Shielding**: To minimize electromagnetic interference, maintain a safe distance between this device and other electronic equipment.
- **Responsibility**: The user is responsible for ensuring that the use of this medical device complies with FCC regulations.

FCC Equipment Authorization Compliance

This medical device has been authorized by the Federal Communications Commission (FCC) in accordance with Part 15 of its regulations. As the manufacturer, we hereby declare that this device complies with FCC rules governing electromagnetic interference.

Responsibilities of the Manufacturer

As the manufacturer, we are responsible for ensuring compliance with FCC regulations. This includes:

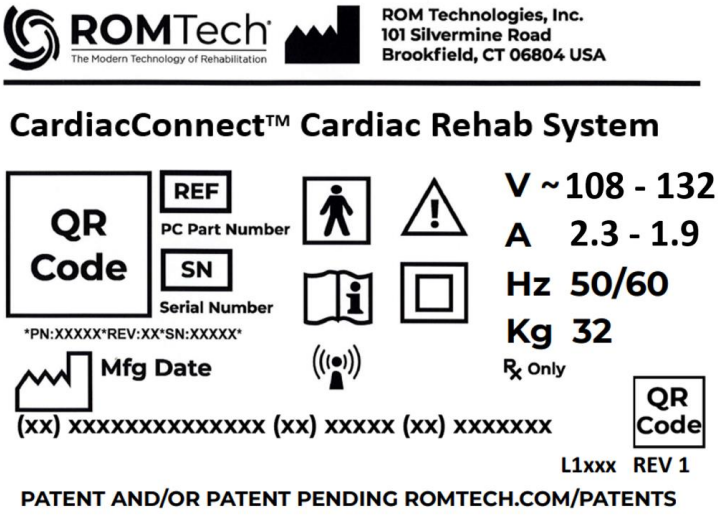
- **Testing**: Conducting testing to ensure that the device meets FCC electromagnetic compatibility requirements.
- **Documentation**: Maintaining records of compliance testing and providing necessary documentation to demonstrate FCC compliance.
- **Labeling**: Ensuring that the device bears the appropriate FCC labeling indicating compliance with Part 15 regulations.
- **Modifications**: Not making modifications to the device that could affect its compliance with FCC rules without appropriate retesting and authorization.

User Responsibilities

As a user of this medical device, you are required to use it in accordance with the provided instructions and guidelines. Any modifications to the device not expressly authorized by the manufacturer may result in non-compliance with FCC regulations.

UDI

The Unique Device Identifier label for the ROMTech CardiacConnect™ is depicted below:



Cybersecurity Update

Any time the software on the CardiacConnect™ updates, you will see the following on the tablet screen:

Questions and Answers

What should I do if the device isn't working?

If you are still having an issue after reviewing the Troubleshooting section, call (888) 457-6430.

How may I get a paper copy of the Instructions for Use?

Call 1 – 888 – 457 – 6430

Where can I get more information about the accessories?

Detailed information about each accessory (including biocompatibility) may be found within the portal.

Who should I call if I have a question about my appointment?

Call (888) 457-6430.

Who should I call if I'm having a medical emergency?

If you are having an emergency before or after your scheduled cardiac rehabilitation session, please call 911.

What is the service life of CardiacConnect?

The CardiacConnect device should last up to five years with proper calibration and servicing.

What should I do when I want CardiacConnect returned?

When your cardiac rehabilitation treatment plan is complete, or if you prefer to stop the plan early, your CRS will arrange for the CardiacConnect device to be removed from your home.