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System Description

The Spaulding Electrocardiograph Model 2100iQ works with the Spaulding webECG Diagnostic ECG management solution. (Medical Device Data System) The lightweight and portable Spaulding Electrocardiograph 2100iQ device* collects and uploads a dedicated patient’s ECG (electrocardiograph) information to the WebECG system and receives a report back from the WebECG system.

The Spaulding Electrocardiograph 2100iQ streams ECG heart rhythm data to a iOS® mobile device using Bluetooth® wireless communication. Using the Spaulding Patient Cable and strategically placed electrodes, it allows the Spaulding Clinical Client Application software (Spaulding ECG) to collect a 12-lead ECG.

The Spaulding ECG application then communicates to the Spaulding webECG server to upload ECG data through an Internet connection.

The complete Spaulding Electrocardiograph 2100iQ Kit includes:

- Spaulding Electrocardiograph 2100iQ device
- Spaulding 12-lead ECG Patient Cable
- USB Cable
- User Manual

The Web ECG system allows users to utilize Internet-based applications that manage the ECG data:

- 3rd party tools and algorithms to analyze acquired data
- Generate diagnostic reports
- Remote access to the stored diagnostic ECGs, webECG reports and Full Disclosure data
- Site management tools to customize the system user interface
- Automated notifications to the care team and remote diagnostics

Intended Use

The Spaulding Electrocardiograph 2100iQ is intended to acquire a resting, diagnostic 12-lead ECG for display and subsequent upload to a Medical Device Data System (MDDS). This enables clinicians, or trained care personnel who are acting on the orders of a licensed physician, to acquire, process, display, store, and print diagnostic 12 lead ECGs.

The Spaulding Electrocardiograph is for use on adult and pediatric populations, diseased or non-diseased and is not intended for use on neonatal (birth to 28 days) or infants (29 days up to 2 years). The device is not for use in highly invasive environments, or as a vital signs physiological monitor.

The Spaulding Electrocardiograph provides un-interpreted 12-lead ECG data and is not to be a sole means of diagnosis.

*Throughout this document, the Spaulding Electrocardiograph Model 2100iQ ECG Device will be referred to as the ECG device.
# Equipment Symbols and Markings

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Info Icon" /></td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td><img src="image" alt="Heart Icon" /></td>
<td>Defibrillator-proof type CF applied part</td>
</tr>
<tr>
<td><img src="image" alt="USB Icon" /></td>
<td>USB Universal Serial Bus</td>
</tr>
<tr>
<td><img src="image" alt="CE Mark" /></td>
<td>CE Mark</td>
</tr>
<tr>
<td><img src="image" alt="Waste Disposal Icon" /></td>
<td>Do not dispose as unsorted municipal waste. Per EC Directive 2002/96, requires separate handling for waste disposal according to national requirements</td>
</tr>
<tr>
<td><img src="image" alt="Warning Icon" /></td>
<td>Consult Information for use. User Manual contains Warnings and Cautions. Failure to adhere to or comply may lead to injury to patient, user or damage to equipment.</td>
</tr>
<tr>
<td><img src="image" alt="EC REP Icon" /></td>
<td>European authorized representative</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer Icon" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Keep Dry Icon" /></td>
<td>Keep Dry</td>
</tr>
<tr>
<td><img src="image" alt="Latex Free Icon" /></td>
<td>Latex Free</td>
</tr>
<tr>
<td><img src="image" alt="UL Classification" /></td>
<td>This device is UL Classified</td>
</tr>
<tr>
<td><img src="image" alt="RF Symbol" /></td>
<td>RF equipment marked with symbol IEC 60417-5140 for non-ionizing radiation.</td>
</tr>
<tr>
<td><img src="image" alt="Bluetooth Symbol" /></td>
<td>Bluetooth® symbol</td>
</tr>
<tr>
<td><img src="image" alt="FCC Icon" /></td>
<td>Federal Communications Commission</td>
</tr>
</tbody>
</table>
User Safety Information

This User Manual provides important information about the use and safety of the Spaulding Electrocardiograph Model 2100iQ ECG Device. Follow all operating procedures. Incorrect use or application of the device, or ignoring specifications and recommendations could result in increased risk of harm to users and/or patients and bystanders. Damage to the ECG device could also occur.

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Means there is the possibility of personal injury to you or others.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAUTION</td>
<td>Means there is the possibility of damage to the device.</td>
</tr>
<tr>
<td>NOTE</td>
<td>Provides information to further assist in the use of the device.</td>
</tr>
</tbody>
</table>

⚠️ WARNINGS

1. The ECG device is for use by qualified medical professionals, trained personnel under the guidance/order of licensed physician. Before attempting to use the Spaulding webECG server for clinical applications, the operator must read and understand the contents of this User Manual and other accompanying documents. Failure to do so could result in increased risk of harm to users and patients or damage to the ECG device.

2. The ECG device captures and presents data showing a patient’s physiological condition that, when reviewed by a trained physician or clinician, can be useful in determining a diagnosis. However, the data should not be used as a sole means for determining a patient’s diagnosis.

3. The quality of the signal produced by the ECG device may be adversely affected by the use of other medical equipment, including, but not limited to, defibrillators, MRI, and ultrasound machines.

4. To prevent electrical interference on the 12-lead ECG, keep the patient cable and ECG device a minimum of 3 feet from any AC powered device while recording ECG data.

5. Device should not be used in an Oxygen rich environment.

6. The device is not designed for use with high frequency (HF), surgical equipment and does not provide a protective means against hazards to the patient. Device has not been tested for magnetic resonance safety. Do not use with MRI systems. For proper operation and the safety of users and patients, equipment and accessories must be connected only as described in this User Manual.

7. The ECG device, however, may be used on patients with an implantable defibrillator. The ECG device provides defibrillation protection only when used with a Spaulding 12-lead ECG Patient Cable. In addition, proper placement of defibrillator paddles when using external defibrillation in relation to the electrodes is required to minimize harm to the patient.

8. The Spaulding 12-lead ECG patient cable includes resistors in each lead for defibrillation protection. 12-lead ECG Patient Cables should be checked for cracks, breakage, or damage of any kind prior to use. Do not use damaged cables, devices, or accessories.

9. Do not attempt to connect the Spaulding 12-lead ECG Patient Cable to any other device other than the Spaulding ECG device.

10. Arrange device cables in order to reduce possibility of patient entanglement or strangulation.

11. Care should be taken to follow proper ECG cable/leadwire connection instructions. Misconnected (e.g. swapped) leadwires can contribute to a physician misdiagnosis.

12. Do not attempt to modify the ECG device, as this can be unsafe for both the user and the patient.
13. To avoid the possibility of serious injury or death, conductive parts of the patient cable, electrodes, and associated connections of Type CF applied parts, including the neutral conductor of the patient cable and electrode should not be exposed to other conductive parts including earth ground.

14. ECG electrodes could cause skin irritation; patients should be examined for signs of inflammation or irritation. Proper clinical procedures must be utilized to prepare the skin of the electrode sites and to monitor the patient for excessive skin irritation, inflammation or other adverse reactions. Electrodes are intended for short-term use and should be removed from the patient promptly following testing.

15. To avoid potential for spread of disease or infection, the ECG device, and Spaulding 12-lead ECG Patient Cable should be cleaned before and after each use. To maintain safety and effectiveness, single-use disposable components beyond their expiration date must not be used. All electrodes and single-use cable/electrodes sets should be properly disposed of after use in accordance with applicable requirements. Single-use disposable components (e.g. electrodes, patient cables, etc.) must not be reused.

16. The USB input and output (I/O) connector is intended for connection to only those devices complying with IEC 60601-1-1, or other IEC standards (e.g., IEC 60950) as appropriate to the device. To reduce any potential risk of electrical shock to the patient, the ECG device is mechanically designed such that the patient connection and the USB connection cannot be made at the same time.

17. To maintain designed operator and patient safety, only use equipment and accessories supplied with the device or specified/approved for use by, Spaulding Clinical Research, LLC.

18. Do not over or under-tighten connections. Do not force or modify connections/connectors.

19. To avoid the possibility of electrical shock, the ECG device must be charged with a IEC 60950 compliant USB wall charger.

20. Failure to follow recommended cleaning procedures, or contact with unspecified cleaning materials/disinfecting agents could result in increased risk of harm to users, patients and bystanders, or damage to the device.

21. Do not operate the equipment if it has been damaged. If equipment is damaged, remove device from service and have device repaired by qualified service personnel.

22. Failure to complete recommended periodic checks/operation/maintenance of equipment can result in increased risk of harm to users and/or patients and bystanders.

23. Avoid the possibility of wireless device interfering with other emergency equipment; test the function in advance to assure compatibility.

24. If multiple serial numbers are shown, choose the correct ECG device serial number (may only happen when devices are paired for the first time). Incorrect choice will result in misidentification of patient information. The serial number is found on the back of the ECG device under the bar code, the 12 character number following S/N.

25. To avoid the potential of compromising patient privacy, use appropriate password security measures, avoid sharing User Credentials, logout of applications after use, and use automated logout security features.

26. Verify the display unit to the correct date/time prior to use with the ECG device.

27. Display unit settings must accommodate local lighting conditions for readability.

28. The ECG device does not contain latex, however, latex allergies can be a serious, potentially life threatening health issue. Those who may be sensitive to latex should not use latex.

29. Operation of the device when user is distracted, fatigued or under the influence of alcohol/drugs can result in increased risk of harm to users and/or patients and bystanders.

30. Keep device away from pets, pests, and children.
CAUTIONS

1. Before use, examine the ECG device and cables for cracks, breaks or other damage. When necessary, dispose of the Spaulding ECG device and 12-lead ECG patient cable in accordance with local regulations.

2. Do not attempt to clean the ECG device or 12-lead ECG patient cables by submersing into any liquid, autoclave, or steam cleaning, as this may damage the device and accessories.

3. Do not use sharp or hard objects to depress the button on the ECG device. Use fingertip only.

4. Use care when connecting the 12-lead ECG Patient Cable and USB cable to the ECG device so that a good connection is made and that the connector pins are not damaged or bent.

5. Do not pull or stretch patient cables in use as this could result in mechanical and/or electrical failures. When not in use, make a loose loop of the 12-lead cables, taking care not to bend or twist tightly. Store the cables with the ECG device.

6. Use the ECG device in a controlled environment, and store according to the published environmental specifications.
   Operating Conditions:
   Ambient Temp: 5°C to 40°C
   Relative Humidity: 15%RH to 93%RH
   Atmospheric Pressure: 700-1060 hPa (up to 3000 m)
   Transport and Storage:
   Ambient Temp: –25°C to 70°C
   Relative Humidity: 5%RH to 93%RH
   Atmospheric Pressure: 700-1060 hPa (up to 3000 m)

7. To protect the ECG device and keep it operational, store device/accessories in a dust-free environment, non-accessible to children or pets.

8. Excessive patient movement could interfere with the operation of the ECG device data collection. Ask the patient to remain still during the ECG data collection.

9. Store electrodes in an airtight container and record date on container. Electrodes dry out when not stored properly causing loss of adhesion, loss of conductivity, resulting in poor quality ECG data.

10. The ECG device does not require special equipment for proper use or maintenance.

11. The ECG device and display unit have no serviceable parts and do not require calibration.

12. Use of accessories, transducers and cables other than those specified or provided by Spaulding Clinical could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

13. To maintain safe and effective operation of equipment, peripheral equipment and accessories that come in direct patient contact must comply with UL 60601-1, IEC 60601-1, IEC 60601-1-11, and IEC 60601-2-25. Use only the equipment and accessories supplied with the device or specified/approved for use by, Spaulding Clinical.

14. All demographic setup changes, except the “Collection Options” column impact the existing database so use caution when making modifications. Please contact Spaulding Clinical Client Services Technical Support at 888-607-7871 or 262-306-3348 with any questions as changes impact the entire database for your organization.
15. 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 the device including cables specified by the manufacturer. Otherwise degradation of the performance of this equipment could result.

16. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary this equipment should be observed to verify that they are operating normally.

NOTES

As defined by IEC 60601-1 and IEC 60601-2-25, the Spaulding ECG device is classified as follows:

- Internally powered equipment.
- Type CF defibrillation-proof applied parts.
- IP22
- Equipment not suitable for use in the presence of a flammable anesthetic mixture.
- Continuous operation.

Proper patient skin preparation is important for correct application of ECG electrodes and operation of the device.

The LED Status Window display on the ECG device automatically turns off (blank screen) if the batteries are depleted. Charge the battery before and after use by connecting to the external USB charger.

Spaulding Clinical recommends having a working back up device in the event of the device failing or becoming inoperative.

Spaulding Clinical ships the ECG device ready to use; no further assembly is required.

Firmware* is managed through the Mason Protocol. When authorized, updates to the firmware occur automatically upon connection to the Mason Protocol. The ECG device firmware version is documented in the patient record.

The typical service life of the ECG device is 2-3 Years (Life of the Internal Li Battery).

The expected service life of the parts and accessories is 2-3 Years (Life of the Internal Li Battery).

The typical operation time of the ECG device is 3-4 hours on full charge.

Recharge time from Depletion to 90% of battery life is 2 hours

The ECG device is compatible with pacemakers.

For assistance needed for setting up, using, or maintaining the device, and to report unexpected operation or events. Contact Spaulding Clinical.

The ECG device enclosure rated to IP22. Protected against insertion of fingers and light splashing water.

Display on ECG device will not power on if device battery has been depleted.

* Firmware is a software program or set of instructions programmed on a hardware device. It provides the necessary instructions for how the device communicates with the other computer hardware, allowing for easy updates.
Spaulding Electrocardiograph Model 2100iQ

Top View
1. LED Status Window
2. Main Function Button

Side View
3. ECG Cable Port
4. USB Cable Port

ECG Device and Display Units

Electrode Connection and Location
5. Spaulding 12-lead ECG Patient Cable
# System Messages

## LED Status Window Indicators - ECG device

<table>
<thead>
<tr>
<th>Display Code</th>
<th>Meaning</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POWER ON/OFF</strong></td>
<td></td>
<td>One long press turns on the ECG device. Another long press turns off the ECG device.</td>
</tr>
<tr>
<td><strong>9</strong></td>
<td><strong>BATTERY CHARGE</strong></td>
<td>One single push of the Main Function button shows a number (0-9) indicating the battery charge level.</td>
</tr>
<tr>
<td><strong>P</strong></td>
<td><strong>PAIRING MODE</strong></td>
<td>Press and hold the Main Function button down until “P,” shows this indicates the ECG device is in Pairing Mode with the Bluetooth device.</td>
</tr>
<tr>
<td><strong>P</strong></td>
<td><strong>PAIRED</strong></td>
<td>“P.” shows that the ECG device and the Bluetooth device are connected.</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td><strong>CHARGING</strong></td>
<td>The ECG device is charging when “C.” shows. When the battery is completely charged, C. will no longer show.</td>
</tr>
<tr>
<td><strong>L</strong></td>
<td><strong>LOW BATTERY</strong></td>
<td>The ECG device battery is too low to record ECGs when “L.” shows.</td>
</tr>
<tr>
<td><strong>U</strong></td>
<td><strong>UPLOAD MODE</strong></td>
<td>“U.” indicates that the firmware* of the ECG device is being updated.</td>
</tr>
</tbody>
</table>

* Firmware is a software program or set of instructions programmed on a hardware device. It provides the necessary instructions for how the device communicates with the other computer hardware, allowing for easy updates.

**NOTE:** Do not unplug USB cable during firmware update.
## System Messages

### Status Messages - Bluetooth Wireless Display Unit

<table>
<thead>
<tr>
<th>Message</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saving ECG:</td>
<td>If the user selects another application on the display unit while ECG waveforms are on screen, ECG data will continue to be saved, only if the acquisition is currently in process. Select the “Saving ECG” message to return to the Spaulding ECG Mobile App.</td>
</tr>
<tr>
<td>Not Saving ECG:</td>
<td>Message on screen until (START SAVING ECG) is selected from the display unit menu.</td>
</tr>
<tr>
<td>Low Battery:</td>
<td>When pairing the Spaulding Electrocardiograph Model 2100IQ ECG Device with the display unit, if (LOW BATTERY) appears on the LED Status Window of the ECG device charge the battery.</td>
</tr>
<tr>
<td>Count Up Timer:</td>
<td>A count-up timer will be shown in the header menu bar of the display unit when the user selects (START SAVING ECG).</td>
</tr>
<tr>
<td>Pace Detection:</td>
<td>The ECG device performs pace detection on leads I and II, covering a minimum pacer range of 250µSec to 2mSec pulse width and 2.0mV to 700mV amplitude. Pulses separated by ≥ to 10m/sec will be detected. A single pace detect will be provided for pacer pulses separated by less than 10m/sec. Pulses will be rejected that do not meet the specified time requirement.</td>
</tr>
</tbody>
</table>

### Icon Definitions for Mobile Display

- **Add New Patient**
- **Enter Patient Demographics**
- **Start Saving ECG**
- **Settings**
- **Search**
- **Stop Saving ECG**
Step One

Electrode Placement

To prepare the skin:

1. Clip excess hair from electrode site; do not shave, as skin may become irritated.
2. Cleanse area with soap and water. Do not use alcohol as skin can become irritated.
3. Remove top layer of skin cells (stratum corneum) using abrasive patch on outside of electrode.
4. Apply electrodes to supine patient per the AHA/IEC lead placement chart below.
   Snap electrodes are required for use with the Spaulding 12 Lead ECG Cable

   NOTE: Check electrode date code and do not use electrodes past the expiration date.

AHA Diagnostic ECG Electrode Placement

<table>
<thead>
<tr>
<th>AHA</th>
<th>Lead Placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>RA</td>
<td>White Right Arm On the fleshy part of the arm between the shoulder and elbow</td>
</tr>
<tr>
<td>LA</td>
<td>Black Left Arm On the fleshy part of the arm between the shoulder and elbow</td>
</tr>
<tr>
<td>RL</td>
<td>Green Right Leg On the fleshy part of the leg between the hip and knee</td>
</tr>
<tr>
<td>LL</td>
<td>Red Left Leg On the fleshy part of the leg between the hip and knee</td>
</tr>
<tr>
<td>V1</td>
<td>Red Fourth space between ribs to the right of the sternum</td>
</tr>
<tr>
<td>V2</td>
<td>Yellow Fourth space between ribs to the left of the sternum</td>
</tr>
<tr>
<td>V3</td>
<td>Green Between leads V2 and V4</td>
</tr>
<tr>
<td>V4</td>
<td>Blue Fifth space between the ribs at the midclavicular line</td>
</tr>
<tr>
<td>V5</td>
<td>Orange Horizontal with V4 at left anterior axillary line</td>
</tr>
<tr>
<td>V6</td>
<td>Purple Horizontal with V5 at midaxillary line</td>
</tr>
</tbody>
</table>
IEC Diagnostic ECG Electrode Placement

<table>
<thead>
<tr>
<th>IEC</th>
<th>Lead Placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>Red Right Arm On the fleshy part of the arm between the shoulder and elbow</td>
</tr>
<tr>
<td>L</td>
<td>Yellow Left Arm On the fleshy part of the arm between the shoulder and elbow</td>
</tr>
<tr>
<td>N</td>
<td>Black Right Leg On the fleshy part of the leg between the hip and knee</td>
</tr>
<tr>
<td>F</td>
<td>Green Left Leg On the fleshy part of the leg between the hip and knee</td>
</tr>
<tr>
<td>C1</td>
<td>Red Fourth space between ribs to the right of the sternum</td>
</tr>
<tr>
<td>C2</td>
<td>Yellow Fourth space between ribs to the left of the sternum</td>
</tr>
<tr>
<td>C3</td>
<td>Green Between leads V2 and V4</td>
</tr>
<tr>
<td>C4</td>
<td>Brown Fifth space between the ribs at the midclavicular line</td>
</tr>
<tr>
<td>C5</td>
<td>Black Horizontal with V4 at left anterior axillary line</td>
</tr>
<tr>
<td>C6</td>
<td>Violet Horizontal with V5 at midaxillary line</td>
</tr>
</tbody>
</table>
Collect ECGs with Mobile Display Unit

The typical healthcare workflow for a diagnostic 12-lead ECG exam starts with a physician's order.

NOTE: The Spaulding Electrocardiograph Model 2100iQ ECG Device is required to stream (deliver via wireless transmission) waveforms to a wireless display unit.

Device Setup
See Spaulding ECG Mobile App Software Installation section.

Data Collection
This section describes the steps required to acquire ECG data from the patient.

1. Press and hold the Main Function button until P (PAIRING MODE) shows as the device pairs with Bluetooth. P (PAIRED) confirms the connection. The device is now ready to start recording ECG data.
   NOTE: If the L (LOW BATTERY) shows on the LED Status Window of the ECG device, or the ECG device itself, does not respond, proceed to charge the battery. Follow the instructions in the Equipment Preparation section.

2. Ensure patient is connected to 12-lead cable and that leads are properly placed. Allow patient to get comfortable. Patient must be very still during data collection.
   CAUTION: Excessive patient movement could interfere with the operation of the ECG device data collection. Ask the patient to remain still during the ECG data collection.

3. Attach the 12-lead ECG Patient Cable to the ECG Cable Port on ECG device as shown in the System Components section.

4. Turn on mobile device and open the Spaulding ECG Mobile App

5. Verify Streaming ECG Data
6. ECG Waveforms will begin to stream and appear on the display unit.

7. Next verify lead quality, by viewing all leads.

8. A flashing message “Not Saving ECG” on the display unit notifies the user when ECG data is not being saved.

9. Select (START SAVING ECG) on the display unit to begin recording the ECG.
   
   NOTE: The Start Saving ECG icon toggles between (START SAVING ECG) and (STOP SAVING ECG). The “Saving ECG” message remains on the display unit during the ECG saving cycle. There is a counter to show how much data has been recorded.

10. When the data collection is complete, select (STOP SAVING ECG) to stop the ECG data collection.

   NOTE: If another application or phone call interrupts the collection of the ECG data on screen, the Spaulding client application will continue running and collecting ECG data in the background. A notification will be sent to the display device’s notification bar and the ECG data will not be lost. The client application can be re-opened at any time to finish the ECG collection and uploading.

   NOTE: If the display device becomes inoperable (e.g. freezes, becomes unresponsive or slow, has wireless connection problems), restart the display device, consulting the manufacturer’s user manual or instructions if needed.
Step Three

Upload ECG and Verify Patient

1. A message “Do you want to upload this ECG?” will display.

2. Select Upload ECG Data to send the ECG data to the Spaulding webECG server.

3. When the upload begins the user selects and confirms an existing order. Select the row containing the correct patient demographics. The Selection Confirmation window will open. Select Continue to confirm or select Cancel to select a different patient. NOTE: If the patient is not displayed in the order list, select (ADD NEW PATIENT) and enter the patient demographic information.

4. The transfer of ECG data will automatically occur between the display unit and the Spaulding webECG server. Depending on the internet connection speed the upload could take up to 1 minute.
5. The report uses Pinch, Zoom and Scroll to allow the user to see the entire report even with a small display. The user may email the png by selecting Email.

New Orders

This procedure is only needed if a physician order has not been entered in advance of the ECG test.

1. Select 👥 (ADD NEW PATIENT).
2. Enter patient information to open fields. Choose Save.
3. The transfer of ECG data will automatically occur between the display unit and the Spaulding webECG server. Depending on the internet connection speed the upload could take up to 1 minute.
4. The report uses Pinch, Zoom and Scroll to allow the user to see the entire report even with a small display. The user may email the png by selecting Email.

Patient Care Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Leads Off/Not Appearing” on display unit</td>
<td>ECG is acquired with some leads missing</td>
<td>Using the live display, ensure all leads are attached to patient appropriately</td>
</tr>
<tr>
<td>Interference causes noise on ECG waveform.</td>
<td>Loose connections on patient electrodes, or patient is not laying still</td>
<td>Ensure leads are attached to patient securely and patient is not moving</td>
</tr>
<tr>
<td>ECG device not pairing with display unit</td>
<td>Other paired display unit within range of ECG device</td>
<td>Ensure that there is only one display unit on, within range of the ECG device while paring</td>
</tr>
<tr>
<td>ECG device does not connect, stream or turn</td>
<td>ECG device is broken</td>
<td>Return to Spaulding</td>
</tr>
<tr>
<td>Square Waves</td>
<td>Lead off, patient cable not connected or broken lead</td>
<td>Check leads and connections. If broken product, do not use device.</td>
</tr>
</tbody>
</table>
Step Four

Review 12-lead Report on Mobile Display Unit

View ECG

The 12-lead ECG data may be reviewed in the png file provided in the Download ECG Window. The 12-lead ECG report can be printed from an attached email or by logging into the Spaulding webECG server.

Off-Line Mode

If the wireless network is not available to upload the ECG data, a message is displayed “Error during ECG upload. The ECG will be archived and an attempt will be made to re-upload it the next time the app is launched.”

When the user selects View Full ECG, a display will be presented which allows the user to view the stored waveforms in a full disclosure viewer.

When the user selects Okay, the ECG data is stored on the display unit until Internet connection is re-established.

NOTE: When the internet connection is re-established and the Spaulding ECG Mobile App is opened, an automatic transfer of ECG data from the display unit to the Spaulding webECG server will occur.
Step Four

Display Units

Cell Phone Display Unit

The user will see the selected default scrolling waveforms—Leads I and II; the user can choose from a menu to view any of the 12 waveforms displayed. Any existing Lead fail message(s) for all leads will be displayed.

Tablet Display Unit in Landscape View

All 12 waveforms are displayed in a split screen format with a vertical dividing bar down the middle of the display. Leads: I, II, III, aVR, aVL, aVF on the left, and leads: V1, V2, V3, V4, V5, V6 on the right (standard 2 x 6 format). If viewing with a tablet or cell phone the waveforms will never shift to a portrait view, even if the display unit is repositioned to a portrait orientation.

NOTE: Based on the size of your tablet, the display may default to the cell phone default display. Select (SETTINGS) to configure your screen format.

Preferences

Select (SETTINGS) to display the following choices for customizing the waveform display.

Pace Detection

The ECG device performs pace detection on leads I and II, covering a minimum pacer range of 250µSec to 2mSec pulse width and 2.0mV to 700mV amplitude. Pulses separated by ≥ 10m/sec will be detected. A single pace detect will be provided for pacer pulses separated by less than 10m/sec. Pulses will not be identified.

Battery Status Indicator

The battery status indicator alerts the user in advance of the ECG device losing power. When a low battery condition occurs pairing with the device and waveforms will be lost. The LED Status Window indicator will display (LOW BATTERY) conditions.
Care and Cleaning

General Care

Inspect equipment daily prior to operation. If you notice anything that requires repair, take the Spaulding Electrocardiograph Model 2100iQ ECG Device out of service and contact Spaulding Clinical.

- Verify that all cables and connectors are securely seated.
- Check the exterior of the ECG device for any visible damage.
- Inspect the 12-lead ECG Patient Cable and connectors for any visible damage.
- Inspect the Main Function button and LED Status Window for proper function and appearance.
- The ECG device has no serviceable parts and calibration is not required. Periodically check functionality of the device by performing a test ECG acquisition and observing the expected results using a non-patient visit designator (e.g. “TEST”).

Cleaning the Patient Cable and the ECG Device

Remove both the USB Cable and the 12-lead ECG Patient Cable from the ECG device before cleaning.

- For general exterior cleaning of the ECG device, the Patient Cable, and leadwires, use a dry, lint-free, soft cloth that is slightly moistened with a mild detergent and warm water solution. Wipe the equipment exterior surfaces and cables with a dry, lint-free, soft cloth and let them air dry. Do not use any excessive drying techniques, such as forced heat.
- Do not spray any cleaning solution directly onto the ECG device. Do not autoclave the 12-lead ECG Patient Cable or ECG device.
- Do not attempt to clean the device or 12-lead ECG Patient Cables by submersing into any liquid, autoclave, or steam cleaning as this may damage the ECG device and accessories.
- Never expose the ECG device or 12-lead ECG Patient Cable to strong ultra violet radiation, as ultra violet radiation may degrade the plastic coating on the module or cable.
## Site Configuration

Review the following minimum mobile display unit specifications to ensure the correct specifications for the display unit hardware and software.

### Minimum Display Unit Specifications

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Display Unit</strong></td>
<td></td>
</tr>
<tr>
<td>International Safety Standards:</td>
<td>Conform to international safety standards for information technology equipment (i.e. IEC 60950)</td>
</tr>
<tr>
<td>Operating System:</td>
<td>The Mason Protocol operates in an iOS-compatible format</td>
</tr>
<tr>
<td>Ram (Memory):</td>
<td>512 MB (minimum)</td>
</tr>
<tr>
<td>Processor:</td>
<td>1 GHz 32-bit or 64-bit processor (minimum)</td>
</tr>
<tr>
<td>Computer Configurations:</td>
<td>Tablet and smart phone based on operating system compatibility</td>
</tr>
<tr>
<td>Internet Compatibility:</td>
<td>Operating system compatible web browser</td>
</tr>
<tr>
<td>Internet Communication:</td>
<td>Secured HTTPS Internet Protocol</td>
</tr>
<tr>
<td>Video Resolution:</td>
<td>1040 x 600 (minimum)</td>
</tr>
<tr>
<td>Disk Space:</td>
<td>1 GB (minimum)</td>
</tr>
<tr>
<td>USB Port:</td>
<td>Connection available for acquired data upload</td>
</tr>
<tr>
<td>Network Connectivity:</td>
<td>Wireless</td>
</tr>
<tr>
<td>Virus Protection:</td>
<td>Recommended</td>
</tr>
<tr>
<td>Apple compatibility:</td>
<td>• Apple iOS 7+ iPhone, iPad Mini</td>
</tr>
<tr>
<td></td>
<td>• Bluetooth 2.0+</td>
</tr>
</tbody>
</table>

⚠️ WARNING: Set the display unit to the correct date/time prior to use with the ECG device.

⚠️ WARNING: Display unit settings must accommodate local lighting conditions for readability.
Spaulding ECG Mobile App Software Installation

Once the site configuration is finalized between the Spaulding Clinical and the site, the Client Services Representative will provide the site login credentials, and a Spaulding Clinical activation code required to install the client application.

Device Setup (One Time)

To install the client application on the mobile display unit, follow these steps:

1. Log into the mobile display unit.
2. Go to iOS App Store and download the Spaulding ECG (Spaulding ECG Mobile App)
3. Once downloaded, open the application and enter the one time activation code given to you from your Spaulding representative. (If you do not have the activation code please contact the Spaulding Client Services help line 262.306.3348).
4. Press and hold the Main Function button until a \( \text{P} \) (PAIRING MODE) appears. \( \text{P} \) (PAIRED) appears that the ECG device and the Bluetooth device are connected.

5. Select Settings on your iOS device and go to Bluetooth settings.

6. Look for the serial number associated with the ECG device and select to Pair the devices.

   **WARNING:** If multiple serial numbers are listed, choose the correct ECG device serial number. Incorrect choice will result in misidentification of patient information. The serial number is found on the back of the ECG device under the bar code, the 12 character number following S/N. Use the numbers following the number 9 until the number 101.

   **NOTE:** The ECG device shares control with the wireless display unit.

7. Once connected, you can exit Settings. As long as you use the same ECG device, and same iOS device you will not need to repeat these steps.

**Display Unit User Identification and Access Permission**

Users may be required to use a login e-mail address and password to access the Spaulding ECG Mobile App. A Spaulding Clinical Client Services Representative provides the site’s user identification and password authorization.

8. Launch the Spaulding ECG Mobile App icon to launch/open the Mason workflow protocol.

9. The Login window will open.

10. Enter login credentials.

   **NOTE:** User login settings are selected in “Site Configuration”.

# Spaulding Electrocardiograph 2100 iQ Specifications

## Electrocardiograph Requirements

### Physical

<table>
<thead>
<tr>
<th>Dimensions:</th>
<th>Portable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3.5 in. diameter x 1 in. (9 cm diameter x 3 cm)</td>
</tr>
<tr>
<td>Unit Weight:</td>
<td>3.5 ounces (100 gms)</td>
</tr>
<tr>
<td>Enclosure:</td>
<td>Water/Particulate ingress rating IP22</td>
</tr>
<tr>
<td>Display:</td>
<td>7 Segment - LED display</td>
</tr>
<tr>
<td>Patient Cable:</td>
<td>■ Shielded, Type CF defibrillation proof</td>
</tr>
<tr>
<td></td>
<td>■ AHA and IEC color codes</td>
</tr>
<tr>
<td></td>
<td>■ EC53 compliant</td>
</tr>
</tbody>
</table>

### Environmental

**Operating:**
- Temperature: +5°C to +40°C (+41°F to +104°F)
- Relative Humidity: 15% to 93%, non-condensing
- Ambient Air Pressure: 700-1060 hPa (up to 3000 m)

**Storage/Transport:**
- Temperature: –25 to +70 °C (–13 to 158 °F)
- Relative Humidity: 5% to 93%, Non-Condensing
- Atmospheric Pressure: 700-1060 hPa (up to 3000 m)

### Performance

**Sampling Rate:** 500 s/sec/channel

**Resolution:** 4.88µV

**Frequency Response:** 0.05 to 250 Hz

**Pacemaker Detection Range:**
- Pulse Width: 250µSec to 2mSec
- Pacer Pulse Amplitude: 2.0mV to 700mV
- Pulse Separation: greater than or equal to 10mSec

**Wilson Leads Acquired:** I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

**A/D Conversion:** 12 bit analog–to–digital converter

**Gain Display Settings:** 2.5, 5, 10, 20, 40 mm/mV

**Display Speed Settings:** 5, 10, 12.5, 25, 50 mm/sec

**Filter:**
- High pass filter to remove baseline wander
- Adaptive band-reject filter for power line noise

**Special Functions:** Baseline recovery circuit

### Power

**Battery Type:**
- Rechargeable lithium ion polymer
- Voltage: 3.7V
- Amperage: 240 mAh
- Recharge Time to 90%: less than 4 hours
## Electrocardiograph Specifications

### Connectivity Bluetooth® Radio

<table>
<thead>
<tr>
<th>Model</th>
<th>Bluegiga WT-12A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmit Power</td>
<td>3.84 dBm E.I.R.B</td>
</tr>
<tr>
<td>Frequency Range</td>
<td>2.402 GHz – 2.480 GHz</td>
</tr>
<tr>
<td>Modulation Technique</td>
<td>Frequency Hopping Spread Spectrum (FHSS) (GFSK)</td>
</tr>
<tr>
<td>Antenna Type</td>
<td>Chip Antenna</td>
</tr>
<tr>
<td>Data Rate</td>
<td>921600 Baud</td>
</tr>
<tr>
<td>Data Flow</td>
<td>Bi-directional</td>
</tr>
<tr>
<td>Protocol</td>
<td>iAP (Proprietary Apple Protocol)</td>
</tr>
<tr>
<td>Security</td>
<td>Bluetooth v2.1 + EDR protocol data encryption</td>
</tr>
<tr>
<td>Microcontroller</td>
<td>Model: Atmel ATxmega64a3u</td>
</tr>
<tr>
<td></td>
<td>Speed: 16 MHz 2xPLL</td>
</tr>
</tbody>
</table>

### Software Requirements

<table>
<thead>
<tr>
<th>Operating System</th>
<th>iOS® 7+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardware</td>
<td>Apple iPhone 6 or iPad Mini</td>
</tr>
<tr>
<td>Storage Space</td>
<td>50MB free space</td>
</tr>
</tbody>
</table>

### Other

<table>
<thead>
<tr>
<th>Service Life</th>
<th>2-3 years (limited by battery)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Time</td>
<td>3-4 hours continuous use from full charge</td>
</tr>
</tbody>
</table>
# Radio Characteristics and General Specifications

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Frequency Range:</td>
<td>ISM Band</td>
</tr>
<tr>
<td>(2400 ... 2483.5) MHz</td>
<td></td>
</tr>
<tr>
<td>Lower Quad Band:</td>
<td>2 MHz</td>
</tr>
<tr>
<td>Upper Quad Band:</td>
<td>3.5 MHz</td>
</tr>
<tr>
<td>Carrier Frequency:</td>
<td>( f = 2402 + k )</td>
</tr>
<tr>
<td>2402 MHz ... 2480 MHz</td>
<td>( k = 0...78 )</td>
</tr>
<tr>
<td>Modulation Method:</td>
<td>GFSK (1 Mbps) P/4 DQPSK (2Mbps)</td>
</tr>
<tr>
<td>Hopping:</td>
<td>1600 hops/s, 1 MHz channel space</td>
</tr>
<tr>
<td>Maximum Data Rate:</td>
<td></td>
</tr>
<tr>
<td>GFSK:</td>
<td>Asynchronous: 723.2 kbps/57.6 kbps</td>
</tr>
<tr>
<td>Synchronous:</td>
<td>433.9 kbps/433.9 kbps</td>
</tr>
<tr>
<td>P/4 DQPSK:</td>
<td>Asynchronous: 1448.5 kbps/115.2 kbps</td>
</tr>
<tr>
<td>Synchronous:</td>
<td>869.7 kbps/869.7 kbps</td>
</tr>
<tr>
<td>8DQPSK:</td>
<td>Asynchronous: 2178.1 kbps/177.2 kbps</td>
</tr>
<tr>
<td>Synchronous:</td>
<td>1306.9 kbps/1306.9 kbps</td>
</tr>
<tr>
<td>Receiving Signal Range:</td>
<td>Typical condition</td>
</tr>
<tr>
<td>–82 to –20 dBm</td>
<td></td>
</tr>
<tr>
<td>Receiver IF Frequency:</td>
<td>Center frequency</td>
</tr>
<tr>
<td>1.5 MHz</td>
<td></td>
</tr>
<tr>
<td>Transmission Power:</td>
<td></td>
</tr>
<tr>
<td>50 ohms</td>
<td></td>
</tr>
<tr>
<td>Compliance:</td>
<td>Bluetooth specification, version 2.0 + EDR</td>
</tr>
<tr>
<td>USB Specification:</td>
<td>USB specification, version 1.1 (USB 2.0 compliant)</td>
</tr>
</tbody>
</table>
Electromagnetic Compatibility

Electromagnetic compatibility with surrounding devices should be assessed when using the Spaulding Electrocardiograph Model 2100iQ ECG Device.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the device according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The device should not be used adjacent to, or stacked on top of other equipment. If the device must be used adjacent to or stacked on top of other equipment, verify that the device operates in an acceptable manner in the configuration in which it will be used.

The use of accessories and cables other than those specified in the Introduction section, may result in increased emissions or decreased immunity of the device.

Guidance and Manufacturer’s Declaration: Electromagnetic Emissions

The ECG device is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment: Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions: CISPR 11</td>
<td>Group 1</td>
<td>The ECG device uses RF energy in the 2.4 GHz Band. Therefore, its RF emissions are not likely to cause harmful interference.</td>
</tr>
<tr>
<td>RF Emissions: CISPR 11</td>
<td>Class B</td>
<td>The ECG device 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.</td>
</tr>
</tbody>
</table>

Guidance and Manufacturer’s Declaration: Electromagnetic Immunity

The ECG device is intended for use in the electromagnetic environment specified below. The customer or user of the ECG device should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment: Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD): IEC 61000-4-2</td>
<td>± 6 kV contact</td>
<td>± 6 kV contact</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>± 8 kV air</td>
<td>± 8 kV air</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
Guidance and Manufacturer’s Declaration: Electromagnetic Immunity

The ECG device is intended for use in the electromagnetic environment specified below. The customer or user of ECG device should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF:</td>
<td>3 Vrms 150 kHz to</td>
<td>3 Vrms (2 Hz, 80%</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the ECG device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>80 MHz</td>
<td>Modulated Test Signal)</td>
<td>Recommended separation distance:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 1.17 \sqrt{P}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 2.23 \sqrt{P}$ 800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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).</td>
</tr>
<tr>
<td>Radiated RF:</td>
<td>10 V/m 80 MHz to 2.7 GHz</td>
<td>3 V/m</td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range†.</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td></td>
<td>1 GHz to 2.7 GHz (2 Hz, 80% Modulated Test Signal)</td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>

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.

* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, ECG device 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

† 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 the Spaulding Electrocardiograph

The Spaulding Electrocardiograph Model 2100iQ ECG Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the ECG device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ECG device as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated Maximum Output Power of Transmitter (W)</th>
<th>Separation Distance According to Frequency of Transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 KHz to 800 MHz</td>
<td>d = 1.17 \sqrt{P} (V1=3)</td>
</tr>
<tr>
<td>80 MHz to 800 MHz</td>
<td>d = 1.17 \sqrt{P} (E1=3)</td>
</tr>
<tr>
<td>800 MHz to 2.5 GHz</td>
<td>d = 2.33 \sqrt{P} (E1=3)</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12 m</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37 m</td>
</tr>
<tr>
<td>1</td>
<td>1.17 m</td>
</tr>
<tr>
<td>10</td>
<td>3.70 m</td>
</tr>
<tr>
<td>100</td>
<td>11.70 m</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined 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 800 MHz, the separation distance for the higher frequency range applies.

NOTE: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE: An additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.
This section is intended to provide the user with information about:
- LED Status Window on the Spaulding Electrocardiograph Model 2100IQ ECG Device
- Charging the Battery via external USB charger

**LED Status Window**

The ECG device uses the LED Status Window to communicate unique status indicators to the user. See the table in the System Messages section.

NOTE: When the ECG device is paired to a display unit, the display unit shows the status message.

**Charging the Battery via External USB Charger**

1. Connect the mini end of the USB Cable to the USB Cable Port on the ECG device.
2. Connect the larger end of the USB Cable to the USB Cable Port on the external USB charger.
3. Ensure the USB Cable connecting the ECG device and the external USB charger is securely connected.
4. Allow the ECG device to charge for a minimum of 20 minutes.
   
   NOTE: Prior to connecting the ECG device to the charger, inspect the USB cable for damage.
   
   NOTE: The LED Status Window shows a blinking dot while the battery is charging and stays solid once the device is charged.
   
   NOTE: If completely depleted, the battery requires a complete charge. The charge time could exceed one hour.
5. After a minimum of 20 minutes has elapsed, disconnect the USB Cable from the USB Cable Ports on the ECG device and the charger.
   
   NOTE: There is no risk associated with leaving the device on a charger for longer than 20 minutes. The device may take up to four hours to completely charge. Once it is completely charged, the flashing light on the display will stop flashing and remain on. At this point, the device will no longer send power to the battery and will use the USB connection solely to keep itself powered on. While there are no risks in the device remaining on a charger after it has been fully charged, its battery can naturally lose a small amount of charge over time when not being used.
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