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Spaulding Electrocardiograph Model 2100iQ User Manual



Part Number 9920-102-02-en August 2026 V20.0

CAUTION: Federal Law restricts this device to sale by or on the order of physician

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System Overview

System Description

The Spaulding Electrocardiograph Model 2100iQ works with the Spaulding webECG Diagnostic ECG management solution. (Medical Device Data System) The light weight 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 rhythms data to iOS®, Android™ or Windows® devices using Bluetooth® wireless communication. Using the Spaulding Patient Cable and strategically placed electrodes, it allows the Spaulding 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 (UI)
- 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 uninterpreted 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

	Consult instructions for use
	Defibrillator-proof type CF applied part
	USB – Universal Serial Bus
	Do not dispose as unsorted municipal waste. Per EC Directive 2002/96, requires separate handling for waste disposal according to national requirements
	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.
	European authorized representative
	Manufacturer
	Keep Dry
	Latex Free
	Bluetooth® symbol
	RF equipment marked with symbol IEC 60417-5140 for non-ionizing radiation.
	Federal Communications Commission

Safety

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.

WARNING	Means there is the possibility of personal injury to you or others.
CAUTION	Means there is the possibility of damage to the device.
NOTE	Provides information to further assist in the use of the device.

⚠ 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 using 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 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 to reduce possibility of patient entanglement or strangulation.
11.	Care should be taken to follow proper ECG cable/lead wire connection instructions. Misconnected (e.g. swapped) lead wires 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 Medical, 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 an 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 as the device is designed to be self-contained with a lifespan of 2-3 years. The worst-case tolerance of all components used in the acquisition circuits yield measured values within IEC 60601.
12.	Use of accessories, transducers and cables other than those specified or provided by Spaulding Medical 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 Medical.
14.	All demographic setup changes, except the “Collection Options” column impact the existing database so use caution when making modifications. Please contact Spaulding Medical Client Services Technical Support 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 Medical recommends having a working back up device in the event of the device failing or becoming inoperative.
Spaulding Medical 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 for continuous usage is 3.5 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 Medical.
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.

System Components

Spaulding Electrocardiograph Model 2100iQ

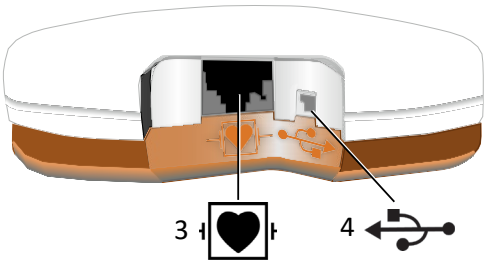
Top View

1. LED Status Window
2. Main Function Button



Side View

3. ECG Patient 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

Display Code	Meaning	Definition
-	***POWER ON/OFF***	One long press turns on the ECG device. Another long press turns off the ECG device.
	***BATTERY CHARGE***	One single push of the Main Function button shows a number (0-9) indicating the battery charge level.
	***PAIRING MODE***	Press and hold the Main Function button until "P" is displayed indicating the ECG device is in Pairing Mode with the Bluetooth device.
	***PAIRED***	The ECG device is connected to the Bluetooth device.
	***CHARGING***	The ECG device is charging. This blinking dot will become solid when the battery is completely charged.
	***LOW BATTERY***	The ECG device battery is too low to record an ECG.
	***UPLOAD MODE***	The ECG device firmware* is being updated. **NOTE:** DO NOT unplug the USB cable during a firmware update.

* 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.

Status Messages – Bluetooth Wireless Display Unit*

Message	Description
SAVING ECG	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 Application.
NOT SAVING ECG	Message on screen until (START SAVING ECG) is selected from the display unit menu.
LOW BATTERY	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.
COUNT UP TIMER	A count-up timer will be shown in the header menu bar of the display unit when the user selects (START SAVING ECG).
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 ≥ 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.

Icon Definitions for Mobile Display

	Add New Patient		Enter Patient Demographics
	Start Saving ECG		Settings
	Search		Stop Saving ECG

* Bluetooth connectivity is required for Android, iOS, or Windows devices to work.

Step One

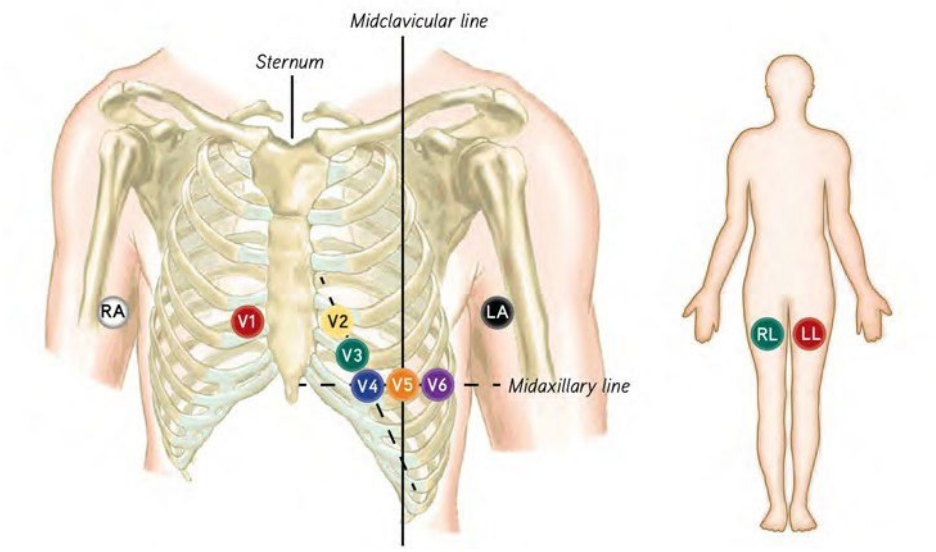
Electrode Placement

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 Patient Cable

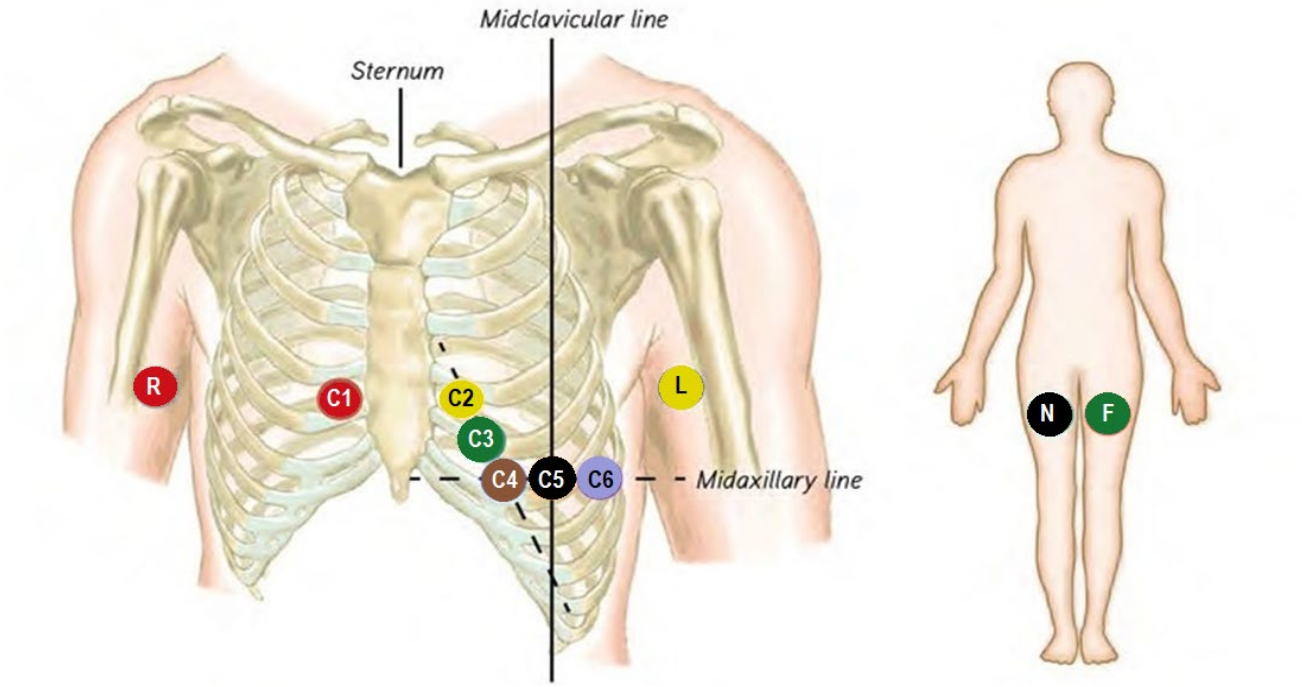
NOTE: Check electrode date code and do not use electrodes past the expiration date.

AHA Diagnostic ECG Electrode Placement



AHA – US/Canada		Lead Placement	
RA	White	Right Arm	On the fleshy part of the arm between the shoulder and elbow
LA	Black	Left Arm	On the fleshy part of the arm between the shoulder and elbow
RL	Green	Right Leg	On the fleshy part of the leg between the hip and knee
LL	Red	Left Leg	On the fleshy part of the leg between the hip and knee
V1	Red		Fourth space between ribs to the right of the sternum
V2	Yellow		Fourth space between ribs to the left of the sternum
V3	Green		Between leads V2 and V4
V4	Blue		Fifth space between the ribs at the midclavicular line
V5	Orange		Horizontal with V4 at left anterior axillary line
V6	Purple		Horizontal with V5 at midaxillary line

IEC Diagnostic ECG Electrode Placement



IEC – Rest of World		Lead Placement	
R	Red	Right Arm	On the fleshy part of the arm between the shoulder and elbow
L	Yellow	Left Arm	On the fleshy part of the arm between the shoulder and elbow
N	Black	Right Leg	On the fleshy part of the leg between the hip and knee
F	Green	Left Leg	On the fleshy part of the leg between the hip and knee
C1	Red		Fourth space between ribs to the right of the sternum
C2	Yellow		Fourth space between ribs to the left of the sternum
C3	Green		Between leads V2 and V4
C4	Brown		Fifth space between the ribs at the midclavicular line
C5	Black		Horizontal with V4 at left anterior axillary line
C6	Violet		Horizontal with V5 at midaxillary line

Note: The above two diagrams/tables show electrode placement for chest and limb-leads based upon the patient cable appropriate for your geographic location. Please be sure to reference the appropriate diagram/table.

- AHA – US/Canada Lead Placement
- IEC – Rest of World Lead Placement

Step Two

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.

Software Installation

See *Spaulding Application* Software Installation sections.

Pairing the Device

To pair your Bluetooth-compatible device with the Spaulding ECG device, follow these steps. Refer to the mobile unit or computer user manual for specific Bluetooth pairing instructions:

1. On your Bluetooth-enabled mobile unit or compatible computer, open the Bluetooth settings.
2. Confirm the ECG device is turned on and the (PAIRING MODE) is visible in the window.
3. Pair the mobile unit or computer with the Spaulding ECG device. (PAIRED) confirms the ECG device connection.
4. The serial number in the Bluetooth list should match the back of the electrocardiograph to ensure proper device is paired.

Application Workflow

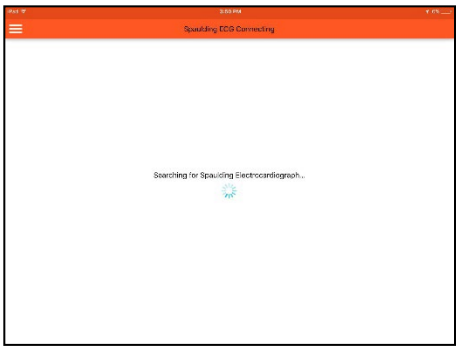
This section describes the steps required to acquire ECG data from the patient.

NOTE: Images may be different from your platform as the User Interface (UI) varies for Windows, Android, and Apple iOS, but the general workflow is the same.

1. Pair the device per the **Pairing the Device** section.

   NOTE: If the (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.

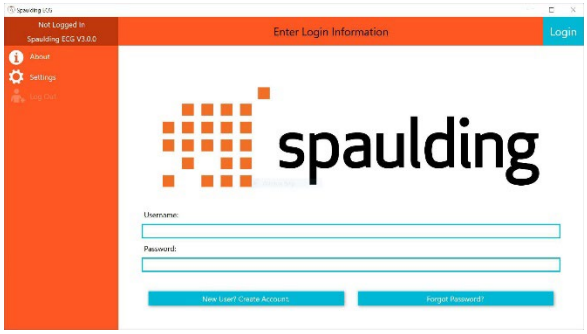
2. Ensure patient is connected to 12-lead Patient Cable and that leads are properly placed. Allow patient to get comfortable. Patient must be very still during data collection.



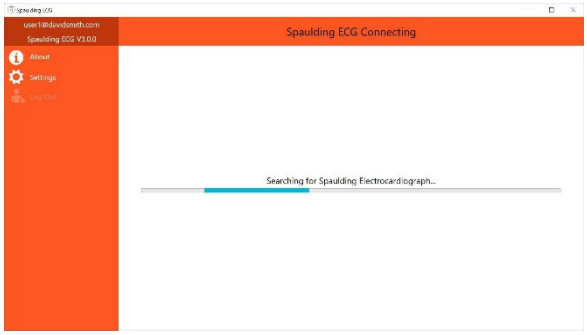
CAUTION: Excessive patient movement could interfere with the operation of the ECG device data collection. Ask the patient to remain still during the ECG data collection.

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 Application**

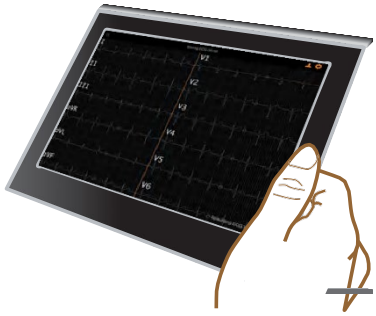
5. You will be presented with a login prompt. Enter the login information for your Spaulding webECG account or use the "New User" button to create a new account through your web browser. Click the "Login" button on the upper right to submit your login information.



6. If the electrocardiograph is not powered on, the application will wait until a connection to the device is made before continuing.



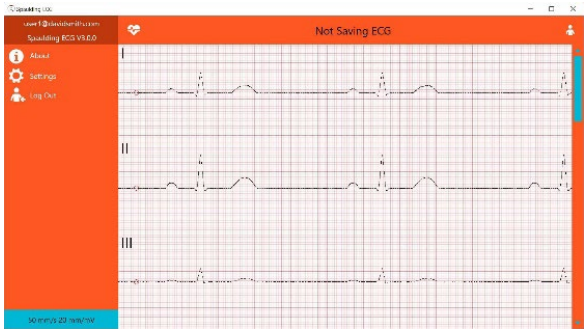
7. Once connected, the live display will show streaming ECG data. Verify the data is streaming and view all leads and verify lead quality. Configure a low-pass filter, if desired (refer to *Configurable Low-Pass Filter Setup* section for instructions).



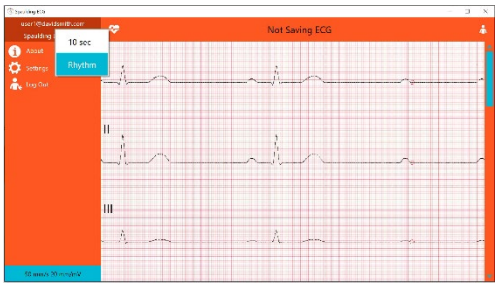


8. The message “Not Saving ECG” will appear at the top of the display unit. Click the (START SAVING ECG) button on the display unit to begin recording the ECG.

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.

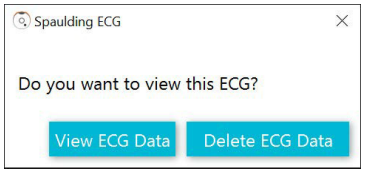


9. Click "10 sec" to quickly acquire 10 seconds of ECG data or "Rhythm" to record any length of ECG data (up to 5 minutes).
10. When the data collection is complete, click the ⏸ (STOP SAVING ECG) button to stop the ECG recording.

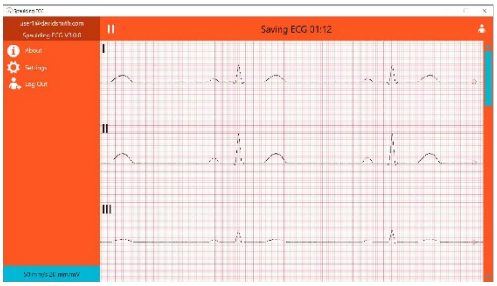
Step Three

Upload ECG and Verify Patient

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

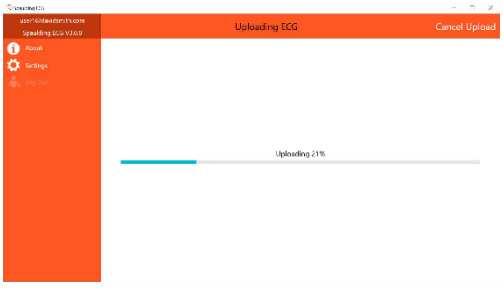


2. Select View ECG Data to review the ECG and ensure the recording length and



quality are acceptable.

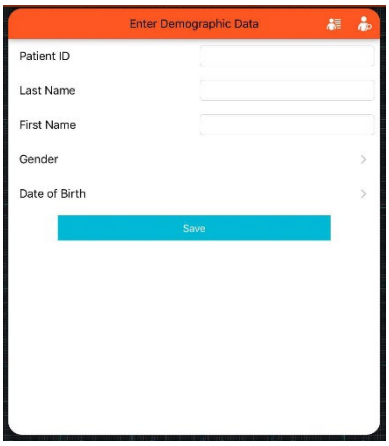
3. Click “Get Report” to send the ECG data to the Spaulding webECG server.
4. When the upload begins, select and confirm an existing order or enter Patient/Subject demographics.
   - Select an order: Select the row containing the correct patient demographics. The Selection Confirmation window will open. Select Continue to confirm or select Cancel to select a different patient. If the patient is not displayed in the order list, refer to the New Orders section.
   - Enter Patient/Subject demographics: Use the button to enter a new subject/ patient or use the button to search for an existing subject/patient. After entering demographic information and reader assignment, if applicable, confirm the information is correct and click “Yes”.



5. 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 a couple minutes.
6. Once uploaded, the ECG Report will appear on screen and is now stored in webECG. The report uses Pinch, Zoom, and Scroll to allow the user to see the entire report even with a small display. To forward the display of the stored 12-lead report in a PNG (Portable Network Graphic), click the share icon in the top right and select email.
7. Press the ← (BACK) button to begin a new acquisition or exit the application if finished.

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 Patient 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.

The report uses Pinch, Zoom and Scroll to allow the user to see the entire report even with a small display. To forward the display of the stored 12-lead report in a PNG format select Email.

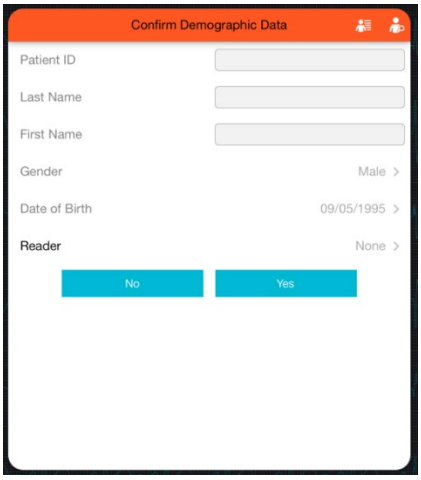
Manual Reader Assignment

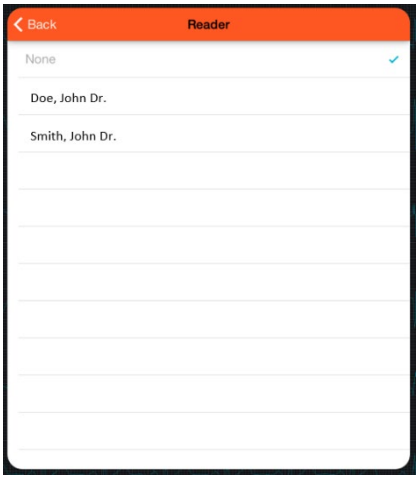
This procedure is only applicable if the site is configured to assign a reader to an ECG from the Client Application. Otherwise, sites are configured to either not send an ECG to a reader or have a designated list of readers to which each ECG is sent.

This feature allows users to choose a specific reader for each ECG either before or after ECG upload.

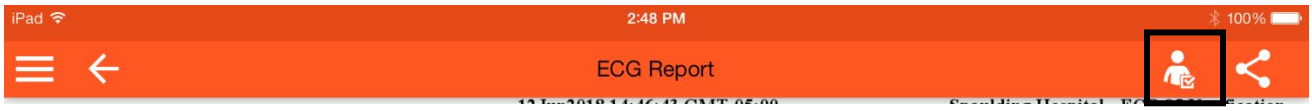
NOTE: If this feature is configured, a reader must be chosen otherwise the ECG will not be reviewed.

1. During demographic entry, select the Reader menu and choose a reader from the provided list.





2. If a reader was not selected during demographic entry, one can be selected from the ECG Report after upload. Click on the reader assignment icon and select a reader from the provided menu.



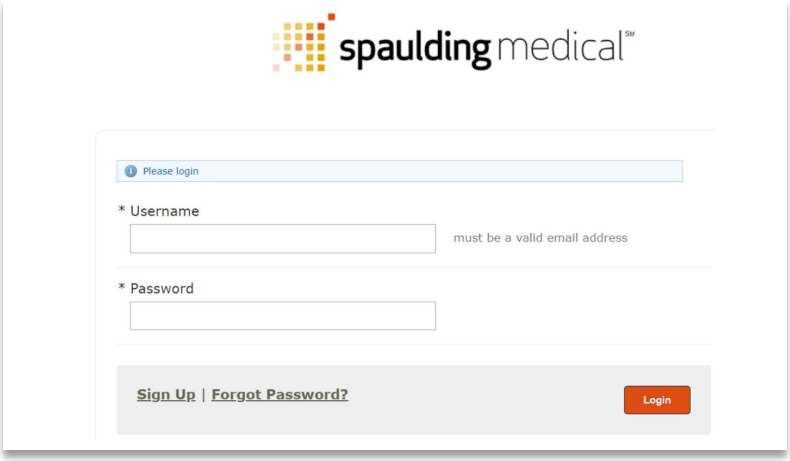
WebECG Instructions for Use

The WebECG application is a web based platform that enables clinicians or trained core personnel who are acting on the orders of a licensed physician to process, display, store, and print diagnostic 12 lead ECGs.

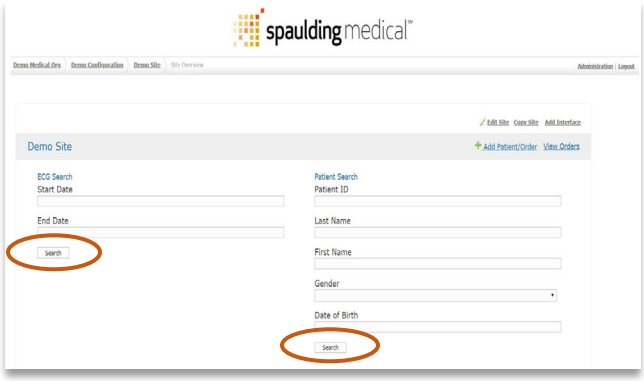
1. Enter “spauldingwebecg.com” into your internet browser. *(Assigned to you by your administrator)*

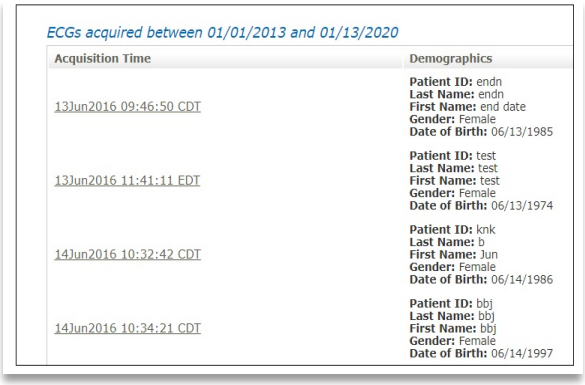


2. Enter your Username and password credentials.

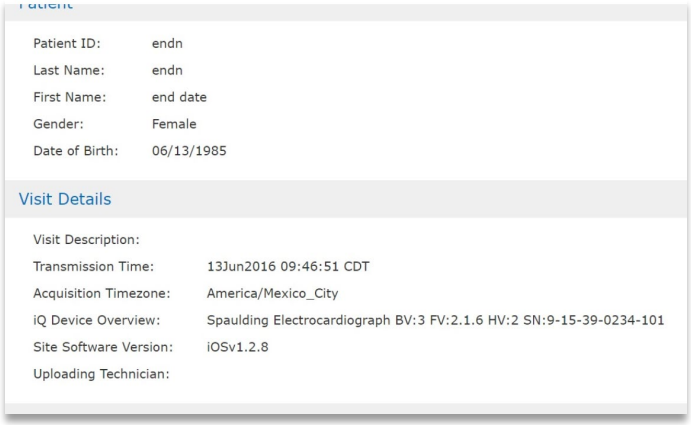


3. Click “Search:” to access ECG’s.





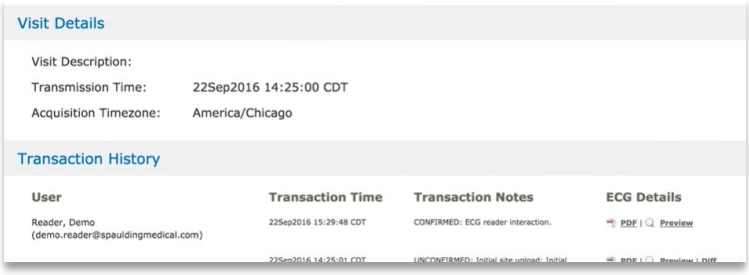
4. ECG Data Information



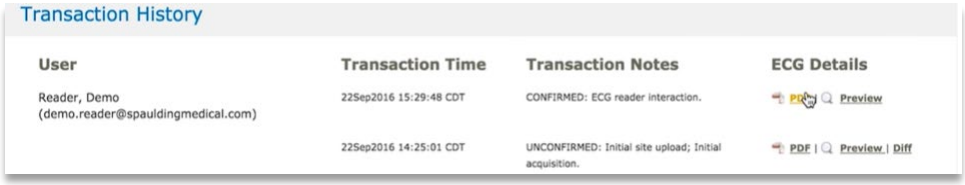
a. Confirmed = Physician Over-Read, Un-Confirmed = Computer Interpretation



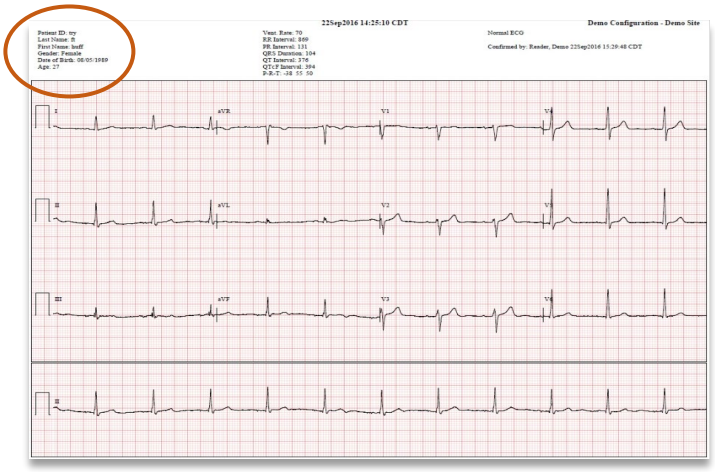
b. Go to Transaction History for Confirmed and Unconfirmed ECG's.



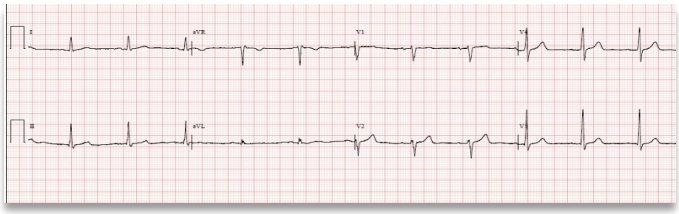
c. Select ECG Details for ECG data.



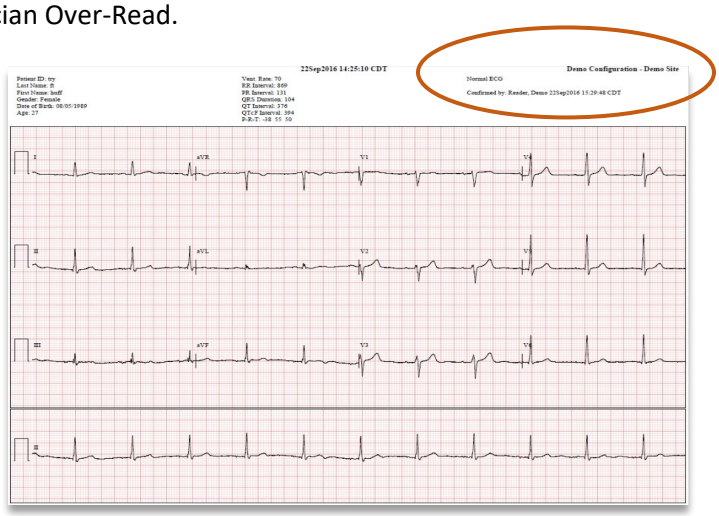
d. Demographics Info located in Upper Left Corner. Emailed ECG's data reduced to Gender and DOB only.



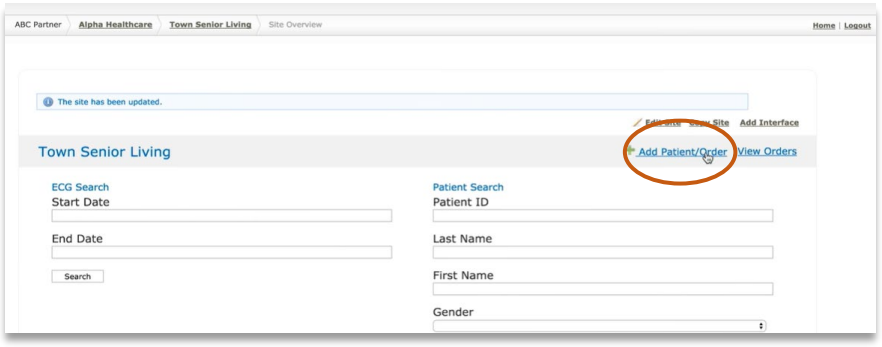
e. Middle section contains ECG Interval Information.



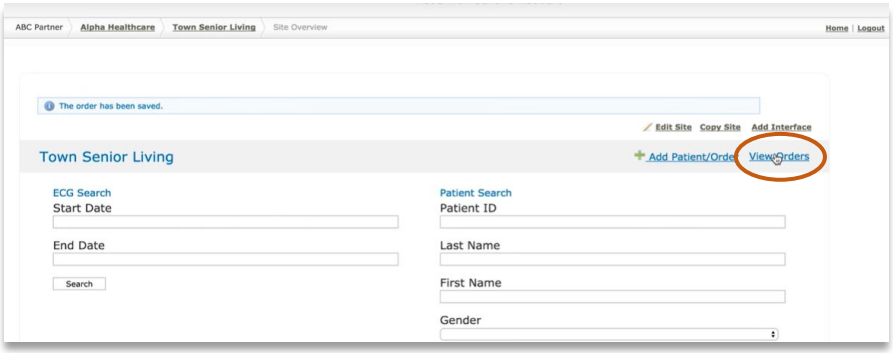
f. ECG Interpretation in top right of screen. Unconfirmed = Computer Interpretation, Confirmed = Physician Over-Read.



5. Select “Add Patient/Order” to add patient information. Select “Save” when complete.



6. Click “View Orders” for patient information. Note: “Orders” are for a onetime ECG collection.



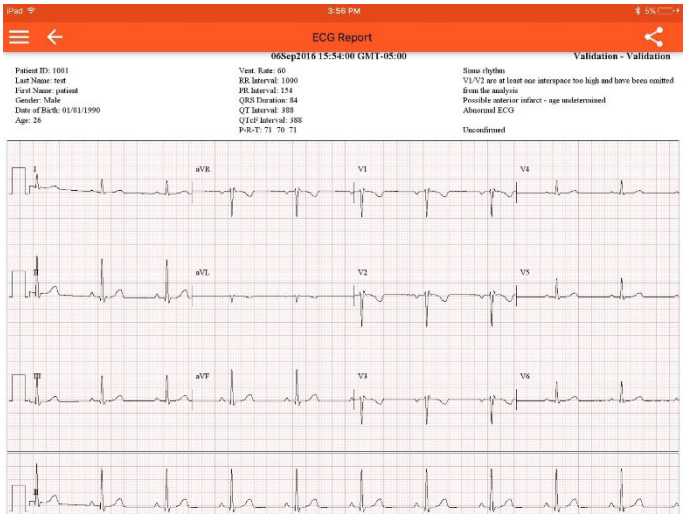
Patient Care Troubleshooting

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

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.

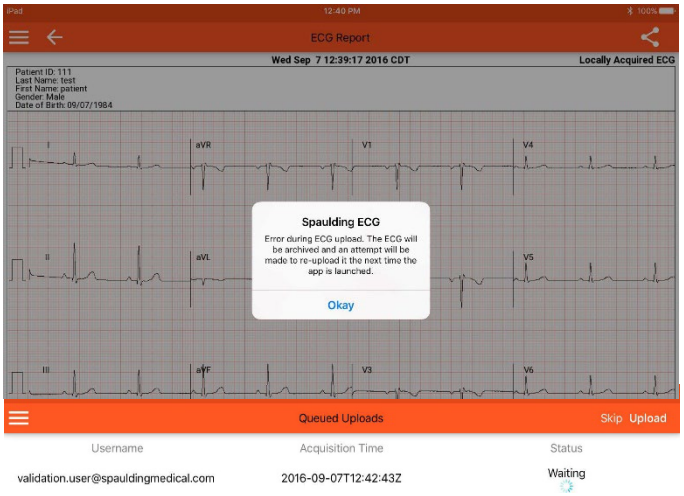
Off-Line Mode

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."

Select View Full ECG, to display the stored waveforms in a full disclosure viewer.

Select Okay, and 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 Application is opened, a listing of queued uploads will be displayed. Click upload in the top right to transfer ECG data from the display unit to the Spaulding webECG server will occur.



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.

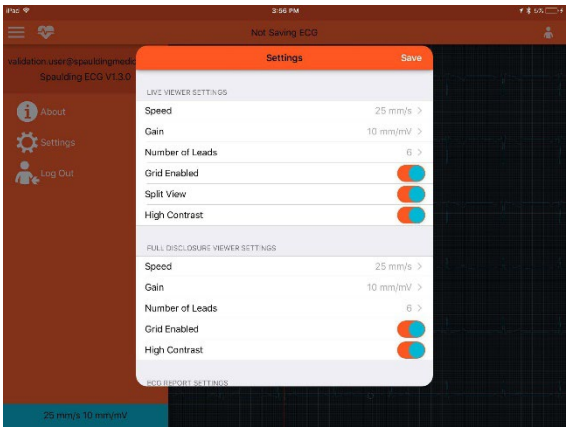
Tablet, Laptop or Desktop Display Unit in Landscape View

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 ≥ to 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 indicatory will display (LOW BATTERY) conditions.

Configurable Low-Pass Filter Setup

webECG

A low-pass filter can only be used if it is first configured within webECG. The default filter setting is “Off” unless manually changed by an administrator to one of the following:

- Off: the low-pass filter is always off
- User Choice: the user can select the desired filter from within the Client Application
- 150 Hz: the filter is always set to 150 Hz
- 100 Hz: the filter is always set to 100 Hz
- 40 Hz: the filter is always set to 40 Hz

To configure a low-pass filter within webECG, perform the following:

1. Log into webECG with provided administrator credentials.
2. Navigate to the desired Protocol or Configuration and click the “Edit Protocol” link in the upper-right.
3. Select the desired low-pass filter setting using the Low Pass Filter Setting dropdown menu.
4. Click the “Update” button at the bottom of the page to save the settings.

Client Application

If the low-pass filter is configured in webECG such that it is always off, 40 Hz, 100 Hz, or 150Hz, no action is required within the Client Application as the setting cannot be changed.

If the low-pass filter is configured in webECG to “User Choice”, the following instructions describe how to change the filter. The chosen filter setting will remain constant until changed by the user or the setting is updated within webECG, so always verify current filter settings prior to ECG acquisition.

1. Log into the Spaulding Client Application with the provided user credentials.
2. Open the Settings menu.
3. Select the desired filter setting form the *Low Pass Filter* option.
4. Close out of the settings menu and the settings will be immediately implemented.

⚠ **WARNING:** The use of a low-pass filter may modify the ECG waveform such that it impacts clinically-significant data.

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 Medical.

- 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 12-lead ECG Patient Cable, and lead wires, 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.

Software Upload

Spaulding Application – Apple iOS

Site Configuration

Review the following minimum Mobile Display Unit specifications to ensure the correct specifications for the display device hardware and software.

Minimum Display Unit Specifications

Feature	Specifications
Apple Display Unit	
International Safety Standards	Conform to international safety standards for information technology equipment (i.e. IEC 60950)
Operating System	iOS 7 or higher
Internet Compatibility	Operating system compatible with web browser
Internet Communication	Secured HTTPS Internet Protocol
Video Resolution	960 x 480 (minimum)
Disk Space	1 GB (minimum)
Network Connectivity	Wireless
Bluetooth	Bluetooth 2.0 or higher

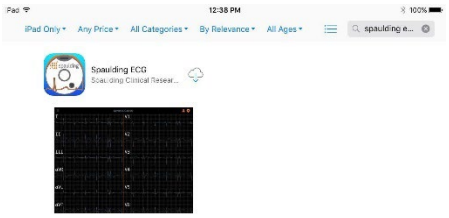
⚠ **WARNING:** Set the display unit to the correct date/time prior to use with the ECG device.

⚠ **WARNING:** Display unit settings must accommodate local lighting conditions for readability.

Spaulding Application Software Installation – Apple

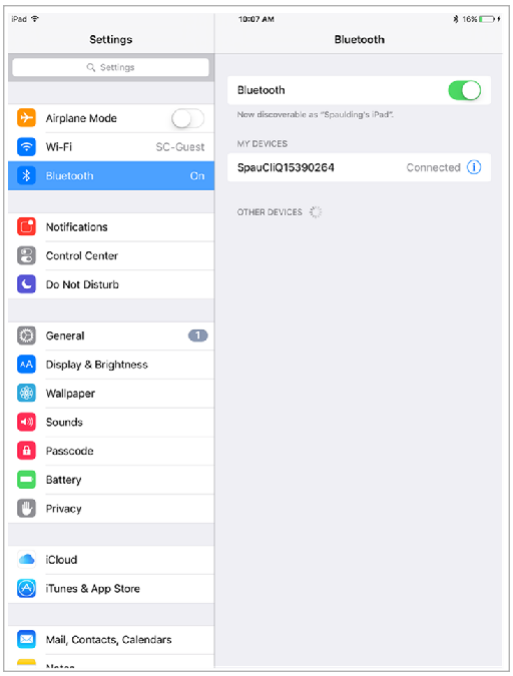
Once the site configuration is finalized between Spaulding Medical and the site, the Client Services Representative will provide the site login credentials required to login to the client application.

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 Application)
3. Once downloaded, open the application and enter the credentials provided to you from your Spaulding representative. (If you do not have user credentials please contact the Spaulding Client Services help line 262-306-3348).
4. Press and hold the Main Function button until a (PAIRING MODE) appears. (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.

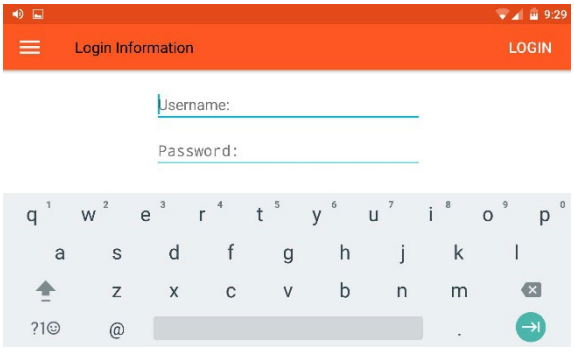
NOTE: The ECG device shares control with the wireless display unit.

7. Once connected, you can exit Settings. If you use the same ECG and iOS devices, 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 Application*. A Spaulding Medical Client Services Representative provides the site's user identification and password authorization.

1. Launch the Spaulding Application icon to launch/open the Mason workflow protocol.
2. The Login window will open.
3. Enter login credentials.



NOTE: User login settings are selected in "Site Configuration".



Spaulding Application – Android OS

Site Configuration

Review the following minimum Mobile Display Unit specifications to ensure the correct specifications for the display device hardware and software.

Minimum Display Unit Specifications

Feature	Specifications
Android Display Unit	
International Safety Standards	Conform to international safety standards for information technology equipment (i.e. IEC 60950)
Operating System	Android 4.2 or higher
Internet Compatibility	Operating system compatible with web browser
Internet Communication	Secured HTTPS Internet Protocol
Video Resolution	800 x 480 (minimum)
Disk Space	1 GB (minimum)
Network Connectivity	Wireless
Bluetooth	Bluetooth 2.0 or higher

⚠ **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.

Important: User should run regular virus checks on all display units that are used with the ECG device to ensure safe/effective operation.

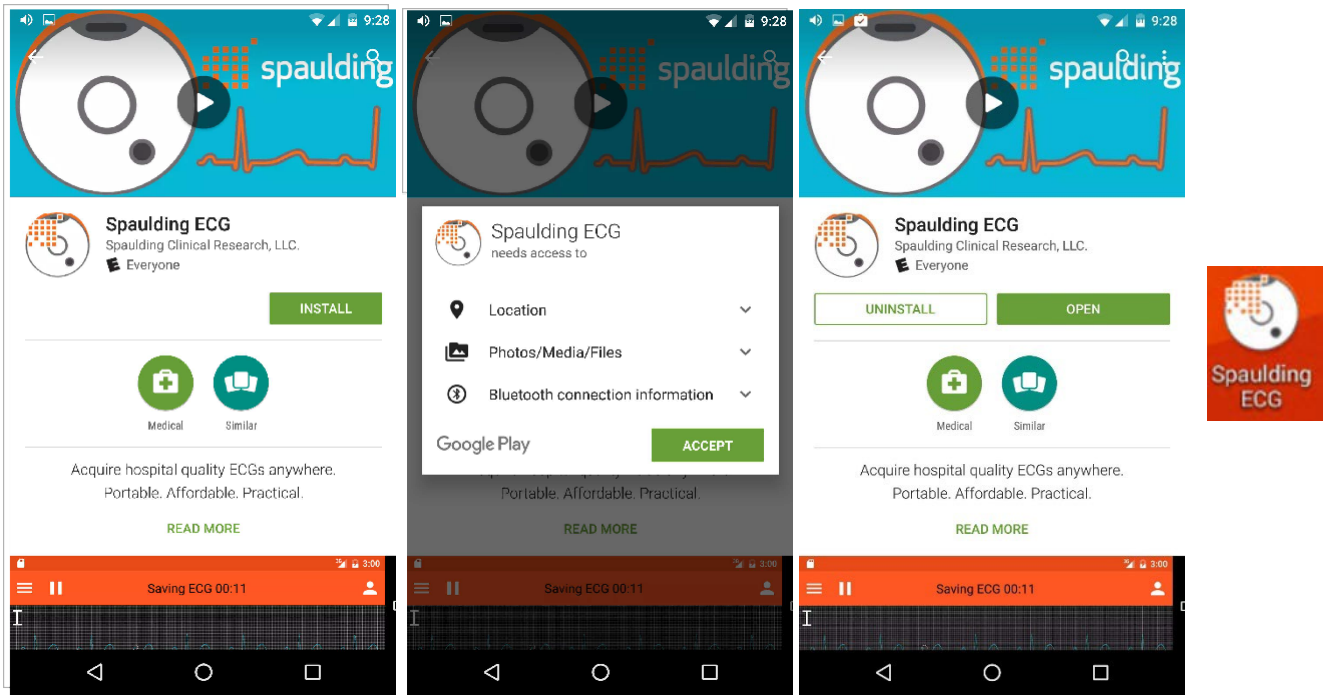
NOTE: Users of the software application are recommended to have their computing environment free of viruses and protected from electronic attacks. Ensure that virus protection software is installed and updated with the latest virus definitions.

Spaulding Application Software Installation – Android

Once the site configuration is finalized between Spaulding Medical and the site, the Client Services Representative will provide the site login credentials required to login to the client application.

To install the Spaulding Application on the Mobile Display Unit, follow these steps:

1. Log into the Mobile Display Unit.
2. Connect to the Google play store.
3. Navigate to the application by typing Spaulding ECG.
4. The client application Installation Overview window will appear. Select Install located at the right of the screen.
5. When the software application has completed the installation progress, the play store will update giving the user the option to Uninstall or Open the application. In addition, the Spaulding Application icon will appear on the screen.



Display Unit User Identification and Access Permission

Users may be required to use a login e-mail address and password to access the *Spaulding Application*. A Spaulding Medical Client Services Representative provides the site's user identification and password authorization.

1. Launch the *Spaulding Application* icon to launch/open the Mason workflow protocol.
2. The Login window will open.
3. Enter login credentials.

NOTE: User login settings are selected in "Site Configuration".

Android is a trademark of Google Inc.

Spaulding Application – Windows OS

Site Configuration

Review the following minimum Mobile Display Unit specifications to ensure the correct specifications for the display device hardware and software.

Minimum Display Unit Specifications

Feature	Specifications
Windows Laptop/Desktop Display Unit	
International Safety Standards	Conform to international safety standards for information technology equipment (i.e. IEC 60950)
Operating System	Windows 7 Service Pack I or higher
Ram (Memory)	1 GB (minimum)
Processor	1 GHz Dual-Core Processor (minimum)
Internet Compatibility	Operating system compatible with web browser
Internet Communication	Secured HTTPS Internet Protocol
Video Resolution	1366 x 768 (minimum)
Disk Space	1 GB (minimum)
Network Connectivity	Wired or Wireless
Bluetooth	Bluetooth 2.0 or higher
Virus Protection	Recommended

⚠ **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.

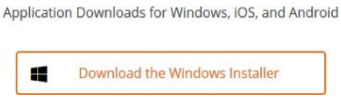
Important: User should run regular virus checks on all display units that are used with the ECG device to ensure safe/effective operation.

Spaulding Application Software Installation– Windows

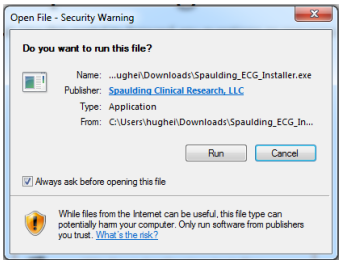
Once the site configuration is finalized between Spaulding Medical and the site, the Client Services Representative will provide the site login credentials, required to login to the client application.

Installing and Launching the Application

1. The Spaulding WebECG Windows application can be downloaded from the Spaulding Medical website. Open a web browser and go to **spauldingmedical.com**. Browse to the Customer Center. On the Customer Center webpage, select the Download the Windows Installer button.



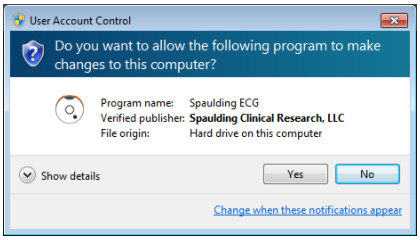
2. After downloading the Windows installer package, run the software to begin the installation process. If Windows prompts with the Open File – Security Warning, select to Run the application.



3. The Spaulding ECG Setup program will prompt to begin the installation. Select to Install the software.



4. At this point, Windows User Account Control (UAC) may prompt to allow the software to make changes to the computer. Select Yes to continue the installation.



5. The Spaulding ECG Setup program will continue and install the software. When the installation is completed, you will be prompted to close the Spaulding ECG Setup program. Select Close and the installation is completed. A desktop icon for the Spaulding ECG software will appear.



6. Double-click the Spaulding ECG icon to 

launch.

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System Information

Spaulding Electrocardiograph Model 2100iQ Specifications

Category	Specification
Physical	
Dimensions	Hand held, portable 3.5 in. diameter x 1 in. (9 cm diameter x 3 cm)
Unit Weight	3.5 ounces (100 g)
Enclosure	Water/Particulate ingress rating IP22
Display	7 Segment - LED display
Patient Cable	■ Shielded, Type CF defibrillation proof ■ AHA and IEC color codes ■ EC53 compliant
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 – 460 mAh ■ **Recharge Time to 90%:** less than 4 hours

Category	Specification
Connectivity Bluetooth® Radio	
Model:	■ Bluegiga WT-12A ■ FCC part 15 compliant
Transmit Power:	3.84 dBm E.I.R.B
Frequency Range:	2.402 GHz – 2.480 GHz
Modulation Technique:	Frequency Hopping Spread Spectrum (FHSS) (GFSK)
Antenna Type:	Chip Antenna
Data Rate:	921600 Baud
Data Flow:	Bi-directional
Protocol:	RFCOMM, iAP (iPod Accessory Protocol for Apple devices)
Security:	Bluetooth v2.1 + EDR protocol data encryption
Microcontroller:	■ **Model:** Atmel ATxmega64a3u ■ **Speed:** 16 MHz 2xPLL
Software Requirements - Apple	
Operating System:	iOS® 7 or higher
Hardware:	iPhone or iPad
Storage Space:	50MB free space
Software Requirements - Android	
Operating System:	Android OS 4.2+
Hardware:	Phone or Tablet
Storage Space:	50MB free space
Software Requirements - Microsoft Windows	
Operating System:	Windows 7 Service Pack 1 or higher
Hardware:	Laptop or Desktop
Storage Space:	50MB free space
Other	
Service Life:	2-3 years (limited by battery)
Operating Time:	Approximately 3.5 hours of continuous use* from full charge

* Operation of the Spaulding Electrocardiograph is typically conducted as intermittent use for collecting 10 seconds or up to 5 minutes of ECG data. When using to collect 10 second ECGs in an intermittent capacity the device can collect ECGs daily for over 30 days. When using to collect 5-minute ECGs in an intermittent capacity the device can collect ECGs daily for over 5 days. It is recommended to charge the device between usage.

Radio Characteristics and General Specifications

Category	Specification		Note
Operating Frequency Range	(2400 … 2483.5) MHz		ISM Band
Lower Quard Band:	2 MHz		
Upper Quard Band:	3,5 MHz		
Carrier Frequency:	2402 MHz ... 2480 MHz		f = 2402 + k, k = 0...78
Modulation Method:	GFSK (1 Mbps) P/4 DQPSK (2Mbps)		
Hopping:	1600 hops/s, 1 MHz channel space		
Maximum Data Rate:	GFSK:	Asynchronous: 723.2 kbps/57.6 kbps Synchronous: 433.9 kbps/433.9 kbps	
	P/4 DQPSK:	Asynchronous: 1448.5 kbps/115.2 kbps Synchronous: 869.7 kbps/869.7 kbps	
	8DQPSK:	Asynchronous: 2178.1 kbps/177.2 kbps Synchronous: 1306.9 kbps/1306.9 kbps	
Receiving Signal Range:	–82 to –20 dBm		Typical condition
Receiver IF Frequency:	1.5 MHz		Center frequency
Transmission Power:	+3 dBm		
RF Input Impedance:	50 ohms		
Compliance:	Bluetooth specification, version 2.0 + EDR		
USB Specification:	USB specification, version 1.1 (USB 2.0 compliant)		

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.

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

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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: 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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF: IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} (2 Hz. 80% Modulated Test Signal)	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. Recommended separation distance: $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.23 \sqrt{P}$ 800 MHz to 2.5 GHz 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*, should be less than the compliance level in each frequency range†. Interference may occur if near equipment marked with the following symbol: 
Radiated RF: IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	3 V/m 30 MHz to 1 GHz 3 V/m 1 GHz to 2.7 GHz (2 Hz. 80% Modulated Test Signal)	

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

NOTE: 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.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 800 MHz $d = 1.17 \sqrt{P}$ (V1=3)	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$ (E1=3)	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$ (E1=3)
0.01	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.37 m	0.737 m
1	1.17 m	1.17 m	2.33 m
10	3.70 m	3.70 m	7.37 m
100	11.70 m	11.70 m	23.30 m

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.

Equipment Preparation

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

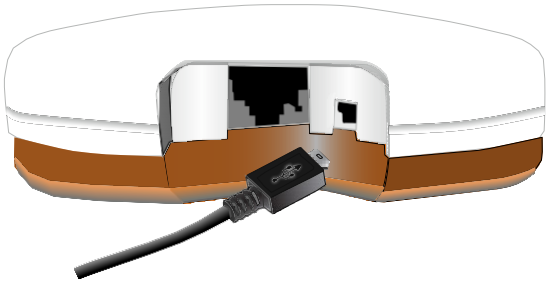
LED Status Window

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.

CAUTION: Use care when connecting the USB cable to the ECG device to ensure the appropriate connection is established and that the connector pins are not damaged or bent.

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Part Number 9920-102-02-en August 2026 V20.0

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