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Introduction

User Manual Purpose

This User Manual is intended to provide the user with information about:

- Using and understanding the Spaulding iQ Electrocardiograph System
- Function and features of the Spaulding iQ ECG Acquisition Module
- Preparation of the Spaulding iQ ECG Acquisition Module
- Patient preparation
- Electrode placement
- Acquiring and storing voice signal and ECG data on the Spaulding iQ ECG Acquisition Module
- Transmitting voice signal and ECG data to the SITE PC
- Installing, using, and understanding the Mason Protocol software application
- Maintenance and troubleshooting

⚠️ WARNING: The Spaulding iQ Electrocardiograph System captures and presents data for review reflecting a patient’s physiological condition. The data, 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.

System Description

The Spaulding iQ Electrocardiograph System is based on two major components:

- A Spaulding iQ ECG Acquisition Module that can acquire the patient demographics by means of an incorporated voice signal input component that uses current industry voice recognition technology and acquire a patient 12-lead ECG.
- A SITE PC located at the participating site, installed with the Mason Protocol, a proprietary Spaulding Clinical, LLC software application that receives ECG data from the Spaulding iQ ECG Acquisition Module and communicates bi-directionally to the Clinical Information Management Server (CIMS) to gather and transfer information concerning the patient’s demographics, visit information, as well as acquired ECG data.

The complete Spaulding iQ Electrocardiograph System includes the Spaulding iQ ECG Acquisition Module with the Spaulding iQ 10-lead Patient Cable [Patient Cable], and the SITE PC with the Mason Protocol software application. The SITE PC software may be installed on an office computer in a non-clinical setting.

Purpose

The intended purpose of the Spaulding iQ Electrocardiograph System is to acquire and digitize 12-lead, resting electrocardiograms along with a voice signature from a patient participating in clinical research protocols or healthcare procedures and to transmit the ECG metadata to the participating SITE PC and CIMS.

Intended Users

The Spaulding iQ Electrocardiograph System is intended to be used by qualified medical professionals or trained personnel who are acting on behalf of the licensed physician.
Indications for Use

The Spaulding iQ Electrocardiograph System is a non-invasive prescriptive device:

- Indicated for use to acquire, analyze, display, and print electrocardiograms
- Indicated for use for pediatric and adult populations, diseased or non-diseased. The device is not indicated for use for neonatal (birth to 28 days) or infants (29 days up to 2 years).
- Indicated for use to provide interpretation of the data for consideration by a physician
- The interpretations of ECG data generated by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- Indicated for use in a clinical setting, by qualified medical professionals who are properly trained in acquiring ECG data and use of the system. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac events. It is not intended as a sole means of diagnosis.
- Not intended to be used as a vital signs physiological monitor
- Not designed for out of hospital transport
- Not designed for use in highly-invasive environments, such as an operating theatre
- The cardiac data and analysis provided by the device must be reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns

Patient Population

The Spaulding iQ Electrocardiograph system is intended for use on a population consisting of patients of any age which may be diseased or non-diseased. The device is indicated for use for pediatric and adult populations, diseased or non-diseased. The device is not indicated for use for neonatal (birth to 28 days) or infants (29 days up to 2 years). Typically, patients are ambulatory, however ECG’s are taken in a resting supine position.

Environment

The Spaulding iQ Electrocardiograph system will typically be used in environments such as hospitals, 24/7 clinics, physician’s offices, or clinics participating in a research protocol during normal office hours.

Methods and Frequency of Use

The Spaulding iQ Electrocardiograph system is intended for use at a frequency defined within research protocols or a physician’s order.

A supplied Spaulding iQ 10-wire Patient Cable connects to the patient with disposable snap-type electrodes (short term Ag/AgCl) and applied to the thorax and limbs, to the Spaulding iQ ECG Acquisition Module for acquisition of ECG data.

The Spaulding iQ ECG Acquisition Module is also used to collect voice signature data from the patient in order to correlate 12-lead ECG data with patient demographic information.
Notifications

Manufacturer’s Responsibility
Spaulding Clinical, LLC is responsible for the effects on patient safety and device performance only if:

- Assembly operations, adjustments, modifications, extensions, or repairs are completed by individuals solely authorized by Spaulding Clinical, LLC.
- The device is used as outlined with this User Manual.

Responsibility of the End User
Individuals who use any component of the Spaulding iQ Electrocardiograph System are responsible for ensuring correct use.

Spaulding iQ Electrocardiograph Acquisition Module Serial Number Identification
The Spaulding iQ Electrocardiograph Acquisition Module is identified by a unique serial number on the back label of the device. Care should be taken to preserve the integrity of this label and to ensure this serial number is not defaced.

Copyright and Trademark Notices
This User Manual contains information that is protected by copyright. All rights reserved. No part of this User Manual may be copied, transmitted, translated to another language, used, or disclosed outside of the intended recipient without the written approval of Spaulding Clinical, LLC.

Other Important Information
The information in this manual is subject to change without further notice. Spaulding Clinical, LLC makes no warranty of any kind with regard to the material including, but not limited to, implied warranties of merchantability and fitness for a particular purpose. Spaulding Clinical assumes no responsibility for any errors or omissions that may appear in this manual or makes no commitment to update or to keep current the information contained in this manual.
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a. Freight damage;
b. Parts and/or accessories of the Product/s not obtained from or approved by Spaulding Clinical Research, LLC;
c. Misapplication, misuse, abuse, and/or failure to follow the Product/s instruction sheets and/or information guides;
d. Accident; a disaster affecting the Product/s;
e. Alterations and/or modifications to the Product/s not authorized by Spaulding Clinical Research, LLC;
f. Other events outside of Spaulding Clinical Research, LLC’s reasonable control or not arising under normal operating conditions.

THE REMEDY UNDER THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT WITHOUT CHARGE FOR LABOR OR MATERIALS, FOR ANY PRODUCT/S FOUND UPON EXAMINATION BY Spaulding Clinical Research, LLC TO HAVE BEEN DEFECTIVE. This remedy shall be conditioned upon receipt of notice by Spaulding Clinical Research, LLC of any alleged defects promptly after discovery thereof within the warranty period.

Spaulding Clinical Research, LLC’s obligations under the foregoing warranty will further be conditioned upon the assumption by the purchaser of the Product/s (i) of all carrier charges with respect to any Product/s returned to Spaulding Clinical Research, LLC’s principal place or any other place as specifically designated by Spaulding Clinical Research, LLC, or an authorized distributor or representative of Spaulding Clinical Research, LLC, and (ii) all risk of loss in transit. It is expressly agreed that the liability of Spaulding Clinical Research, LLC is limited and that Spaulding Clinical Research, LLC does not function as an insurer.

A purchaser of a Product/s, by its acceptance and purchase thereof, acknowledges and agrees that Spaulding Clinical Research, LLC is not liable for loss, harm, or damage due directly or indirectly to an occurrence or consequence therefrom relating to the Product/s. If Spaulding Clinical Research, LLC should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Spaulding Clinical Research, LLC shall be limited to the lesser of the actual loss, harm, or damage, or the original purchase price of the Product/s when sold.

EXCLUDED FROM THE LIMITED WARRANTY SET FORTH ABOVE ARE CONSUMABLE ITEMS SUCH AS ELECTRODES, PATIENT CABLES, AND USB CABLES WHICH ARE LIMITED TO NINETY (90) DAYS FROM THE DATE OF RECEIPT BY PURCHASER (NOT TO EXCEED 120 DAYS FROM DATE OF SHIPMENT BY SPAULDING CLINICAL RESEARCH, LLC).

EXCEPT AS SET FORTH HEREIN WITH RESPECT TO REIMBURSEMENT OF LABOR CHARGES, A PURCHASER’S SOLE EXCLUSIVE REMEDY AGAINST SPAULDING CLINICAL, LLC FOR CLAIMS RELATING TO THE PRODUCT/S FOR ANY AND ALL LOSSES AND DAMAGES RESULTING FROM ANY CAUSE SHALL BE THE REPAIR OR REPLACEMENT OF DEFECTIVE PRODUCT/S TO THE EXTENT THAT THE DEFECT IS NOTICED AND SPAULDING CLINICAL, LLC IS NOTIFIED WITHIN THE WARRANTY PERIOD. IN NO EVENT, INCLUDING THE CLAIM FOR NEGLIGENCE, SHALL SPAULDING CLINICAL, LLC BE LIABLE FOR INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, OR FOR ANY OTHER LOSS, DAMAGE, OR EXPENSE OF ANY KIND, INCLUDING LOSS OF PROFITS, WHETHER UNDER TORT, NEGLIGENCE OR STRICT LIABILITY THEORIES OF LAW, OR OTHERWISE. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.
# Equipment Symbols and Markings

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>📚</td>
<td>Consult Information for Use</td>
</tr>
<tr>
<td>💥</td>
<td>Defibrillator-proof type CF applied part</td>
</tr>
<tr>
<td>🎤</td>
<td>Microphone for Voice Detection</td>
</tr>
<tr>
<td>🌐</td>
<td>USB Universal Serial Bus</td>
</tr>
<tr>
<td>🚫</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>🚨</td>
<td>Manual contains Warnings and Cautions. Failure to adhere to or comply may lead to injury to patient, user or damage to equipment.</td>
</tr>
</tbody>
</table>

### Wellkang Ltd

Suite B, 29 Harley Street  
London, W1G 9QR, U.K.

### Spaulding Clinical, LLC

525 South Silverbrook Drive  
West Bend, Wisconsin 59095  
USA
This User Manual provides important information about the use and safety of the Spaulding iQ Electrocardiograph System. Please read the following patient and end user safety information before use.

**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***

This User Manual provides important information about the use and safety of the Spaulding iQ Electrocardiograph System. Deviating from operating procedures, misuse or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users and or patients and bystanders, or damage to the Spaulding iQ ECG Acquisition Module.

The Spaulding iQ ECG Acquisition Module captures and presents data reflecting 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.

The Spaulding iQ Electrocardiograph System is intended to be used by qualified medical professionals or trained personnel who are acting on behalf of the licensed physician. Before attempting to use the Spaulding iQ Electrocardiograph system 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 Spaulding iQ ECG Acquisition Module.

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

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

The Spaulding iQ ECG Acquisition Module is neither designed to detect or reject Pacemaker signals. There is no known safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.

To avoid the possibility of serious injury or death during patient defibrillation, do not come in contact with device or patient cables. In addition, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.

The Spaulding iQ ECG Acquisition Module is not intended to be connected to patients in need of defibrillation. However, the Spaulding iQ ECG Acquisition Module may be used on patients with an implantable defibrillator. The Spaulding iQ ECG Acquisition Module provides defibrillation protection only when used with the Spaulding Clinical, LLC Spaulding iQ 10-lead Patient Cable.

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.

Patient cables intended for use with the device include series resistance (9 Kohm minimum) in each lead for defibrillation protection. Patient cables should be checked for cracks or breakage prior to use.
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 come into contact with other conductive parts including earth ground.

ECG electrodes could cause skin irritation; patients should be examined for signs of inflammation or irritation. Proper clinical procedures must be utilized to prep 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. To avoid potential for spread of disease or infection, single-use disposable components (e.g. electrodes) must not be reused. To maintain safety and effectiveness, electrodes must not be used beyond their expiration date.

A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

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 Acquisition Module is mechanically designed such that the patient connection and the USB connection cannot be made at the same time.

To maintain designed operator and patient safety, peripheral equipment and accessories used that can come in direct patient contact must be in compliance with UL 60601-1, IEC 60601-1, and IEC 60601-2-25. Only use parts and accessories supplied with the device and available through Spaulding Clinical LLC.

Do not attempt to connect patient cable to any other device other than the Acquisition Module.

⚠️ CAUTIONS

No user calibration or special equipment is needed for the proper operation or maintenance of the Spaulding iQ Electrocardiograph System.

The Spaulding iQ ECG Acquisition Module and SITE PC have no serviceable parts and calibration is not required.

Do not use sharp or hard objects to depress Spaulding iQ ECG Acquisition Module button; use only fingertips.

Do not attempt to clean the device or patient cables by submersing into any liquid, autoclave, or steam cleaning as this may damage the Spaulding iQ ECG Acquisition Module.

To avoid potential for spread of disease or infection, the Spaulding iQ ECG Acquisition Module, Patient Cables, and lead wires should be cleaned between each use.

When necessary, dispose of the Spaulding iQ ECG Acquisition Module and patient cables in accordance with local regulations.

The Acquisition Module will go into a sleep mode to preserve the battery life after a period of inactivity. A completed recording (voice and ECG) is retained indefinitely in the case of a depleted battery.

Electrodes should be stored in an air-tight container. Electrodes will dry out if not stored properly which will cause loss of adhesion and conductivity.

Use care when connecting the USB Cable to the Spaulding iQ ECG Acquisition Module to ensure the appropriate connection is established and that the connector pins are not damaged or bent.

Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Patient cables should be stored with the Spaulding iQ ECG Acquisition Module after forming a loose loop in the cords.
The Spaulding iQ ECG Acquisition Module is intended to be used in a clinic setting, and should be used and stored according to the environmental conditions specified below:

### Operating
- **Temperature**: +0 to +45 °C (+32 to +113 °F)
- **Relative Humidity**: 10% to 95%, Non-condensing
- **Ambient Air Pressure**: 700 to 1060 millibars

### Storage
- **Temperature**: –20 to +65 °C (–4 to 149 °F)
- **Relative Humidity**: 5% to 95%, Non-Condensing
- **Ambient Air Pressure**: 700 to 1060 millibars

### NOTES
As defined by IEC 60601-1 and IEC 60601-2-25, the Spaulding iQ ECG Acquisition Module is classified as follows:
- Internally powered equipment.
- Type CF defibrillation-proof applied parts.
- Ordinary equipment.
- Equipment not suitable for use in the presence of a flammable anesthetic mixture.
- Continuous operation.

Excessive patient movement could interfere with the operation of the Spaulding iQ ECG Acquisition Module ECG collection. Ask the patient to remain still during the ECG data collection period.

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

The device will automatically turn off (blank screen) if the batteries have been severely discharged.

After operating the device using battery power, connect to the SITE PC to charge ("C") the battery.

The Spaulding iQ ECG Acquisition Module is distributed ready to use. No further assembly is required by the end user.

The Spaulding iQ ECG Acquisition Module firmware is managed through the Mason Protocol. When authorized, updates to the firmware occur automatically upon connection to the Mason Protocol. The Acquisition Module firmware version is documented in the patient record.

This device is UL Classified.
Electromagnetic Compatibility

Electromagnetic compatibility with surrounding devices should be assessed when using the Spaulding iQ ECG Acquisition Module.

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 below, may result in increased emissions or decreased immunity of the device.

<table>
<thead>
<tr>
<th>Description</th>
<th>Part Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spaulding iQ 10-lead Patient Cable AHA</td>
<td>WR0458CS</td>
</tr>
<tr>
<td>Spaulding iQ 10-lead Patient Cable IEC</td>
<td>WR0459CS</td>
</tr>
<tr>
<td>USB Cable</td>
<td>WR0457CS</td>
</tr>
</tbody>
</table>

Guidance and Manufacturer’s Declaration: Electromagnetic Emissions

The Spaulding iQ ECG Acquisition Module 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</td>
<td>Group 1</td>
<td>The Spaulding iQ ECG Acquisition Module uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic Emissions</td>
<td>Not Applicable</td>
<td>The Spaulding iQ ECG Acquisition Module 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>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations/ Flicker Emissions</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Guidance and Manufacturer’s Declaration: Electromagnetic Immunity

The Spaulding iQ ECG Acquisition Module 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 Level</th>
<th>Compliance</th>
<th>Electromagnetic Environment: Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV contact</td>
<td>± 6 kV</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>IEC 61000-4-2</td>
<td>± 8 kV air</td>
<td>± 8 kV</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td></td>
<td>Participating SITE PC must meet the criteria under IEC 60950</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td></td>
<td>Participating SITE PC must meet the criteria under IEC 60950</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions, and voltage variations on power supply input lines</td>
<td>Participating SITE PC must meet the criteria under IEC 60950</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</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 Spaulding iQ ECG Acquisition Module 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>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conducted RF</strong></td>
<td>IEC 61000-4-6</td>
<td></td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td></td>
<td>3 Vrms</td>
<td>3 Vrms</td>
<td>Recommended separation distance:</td>
</tr>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
<td>150 kHz to 80 MHz</td>
<td>$d = \left[ \frac{3.5}{3 \text{Vrms}} \right] \sqrt{P}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = \left[ \frac{3.5}{3 \text{Vrms}} \right] \sqrt{P}$ 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = \left[ \frac{7}{3 \text{V/m}} \right] \sqrt{P}$ 800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td><strong>Radiated RF</strong></td>
<td>IEC 61000-4-3</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). 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 in the vicinity of equipment marked with the following symbol:</td>
</tr>
<tr>
<td></td>
<td>3 V/m</td>
<td>3 V/m</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td></td>
<td>80 MHz to 2.5 GHz</td>
<td>80 MHz to 2.5 GHz</td>
<td></td>
</tr>
</tbody>
</table>

* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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 iQ ECG Acquisition Module

The Spaulding iQ ECG Acquisition Module is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended in the table 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></td>
<td>150 KHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td>d = 1.2 √P</td>
</tr>
<tr>
<td>0.01</td>
<td>0.1 m</td>
</tr>
<tr>
<td>0.1</td>
<td>0.4 m</td>
</tr>
<tr>
<td>1</td>
<td>1.2 m</td>
</tr>
<tr>
<td>10</td>
<td>4.0 m</td>
</tr>
<tr>
<td>100</td>
<td>12.0 m</td>
</tr>
<tr>
<td></td>
<td>800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td></td>
<td>d = 2.3 √P</td>
</tr>
<tr>
<td>0.01</td>
<td>0.2 m</td>
</tr>
<tr>
<td>0.1</td>
<td>0.7 m</td>
</tr>
<tr>
<td>1</td>
<td>2.3 m</td>
</tr>
<tr>
<td>10</td>
<td>7.0 m</td>
</tr>
<tr>
<td>100</td>
<td>23.0 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 estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.
General Care and Cleaning Instructions

General Care
Inspect your equipment daily prior to operation. If you notice anything that requires repair, take the Spaulding iQ ECG Acquisition Module out of service and contact Spaulding Clinical, LLC.

- Verify that all cables and connectors are securely seated.
- Check the exterior of the Spaulding iQ ECG Acquisition Module for any visible damage.
- Inspect the Patient Cable and connectors for any visible damage.
- Inspect the Main Function Button Light Emitting Diode (LED) Display for proper function and appearance.
- The Spaulding iQ ECG Acquisition Module has no serviceable parts and calibration is not required. Periodically check functionality of the Acquisition Module by performing a test Voice/ECG acquisition and observing the expected results using a TEST visit.

Cleaning the Patient Cable and the Acquisition Module

⚠️ WARNING: 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.

⚠️ CAUTION: Do not attempt to Sterilize. Do not attempt to clean the device or patient cables by submersing into any liquid, autoclave, or steam cleaning as this may damage the Spaulding iQ ECG Acquisition Module.

⚠️ CAUTION: To avoid potential for spread of disease or infection, the Spaulding iQ ECG Acquisition Module, Patient Cables, and lead wires should be cleaned between each use.

Methods
Remove both the USB Cable and the Patient Cable from the Spaulding iQ ECG Acquisition Module before cleaning. For general exterior cleaning of the Spaulding iQ ECG Acquisition Module, the Patient Cable, and lead wires, use a lint-free soft cloth that is slightly moistened with a mild soap and water solution. Wipe the equipment 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 Spaulding iQ ECG Acquisition Module. Do not autoclave the Patient Cable or Spaulding iQ ECG Acquisition Module.
- **Do not** attempt to disinfect the Spaulding iQ ECG Acquisition Module, Patient Cable, or lead wires by immersing into any liquid, autoclave or steam cleaning as this may damage equipment or reduce its usable life. Wipe the exterior surfaces with a warm water and mild detergent solution and then dry with a clean cloth.
- **Never** expose the Spaulding iQ ECG Acquisition Module or Patient Cable to strong ultra violet radiation, as ultra violet radiation may degrade the plastic coating on the module or cable.
**System Description**

The Spaulding iQ Electrocardiograph System is a 12-lead diagnostic electrocardiograph and voice signal recorder capable of acquiring, storing and transmitting ECG and voice signal data.

The Spaulding iQ Electrocardiograph System includes the following components:

<table>
<thead>
<tr>
<th>Description</th>
<th>Part Numbers</th>
</tr>
</thead>
</table>
| **Spaulding iQ ECG Acquisition Module Kit** | KT-1020973-AHA  
KT-1020973-IEC                   |
| **Spaulding iQ 10-wire Patient Cable**   | AHA: WR0458CS  
IEC: WR0459CS                      |
| **USB Cable**                            | WR0457CS                          |
| **Disposable snap-type electrodes**      | Call Spaulding Client Services &  
Technical Support Group  
1-888-607-7871 to reorder electrodes |
| **User Manual**                          | 9920-101-02-eng                   |
| **Spaulding iQ Electrocardiograph System SITE PC Installation and Start Up Instructions** | 9920-101-04-eng                   |
| **CD Label and Assembly**                | 9920-101-07-eng                   |
Spaulding iQ ECG Acquisition Module

Spaulding iQ ECG Acquisition Module (Top View)

Spaulding iQ ECG Acquisition Module (Side View)
Spaulding iQ ECG Acquisition Module Specifications

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating Modes and Features</strong></td>
<td></td>
</tr>
<tr>
<td>Device Classification Specification</td>
<td>Class I, type CF Defibrillation-proof applied parts</td>
</tr>
<tr>
<td>Instrument Type</td>
<td>12-lead Electrocardiograph</td>
</tr>
<tr>
<td>Input Channels</td>
<td>5-minute, simultaneous acquisition of all 12-leads 30-second voice signal recording</td>
</tr>
<tr>
<td>Standard Leads Acquired</td>
<td>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6</td>
</tr>
<tr>
<td>Storage Capacity</td>
<td>Up to 30-second voice signal and 5-minutes ECG data</td>
</tr>
<tr>
<td>Operator Message Display</td>
<td>7-segment LED Display Window</td>
</tr>
<tr>
<td>Operator Interface Controls</td>
<td>Front panel touch button</td>
</tr>
<tr>
<td>A/D Conversion</td>
<td>12 bits (2.664 microvolt LSB)</td>
</tr>
<tr>
<td>Digital Sampling Rate</td>
<td>1000 s/sec/channel</td>
</tr>
<tr>
<td>Frequency Response</td>
<td>0.05 to 150 Hz</td>
</tr>
<tr>
<td>Special Functions</td>
<td>Integrated Lead Quality Check, High performance baseline recovery</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td></td>
</tr>
<tr>
<td>Battery Type</td>
<td>Internal lithium polymer battery</td>
</tr>
<tr>
<td>Sleep Mode</td>
<td>The Acquisition Module will go into a sleep mode to preserve the battery life after a period of inactivity. A completed recording (voice and ECG) is retained indefinitely in the case of a depleted battery.</td>
</tr>
<tr>
<td><strong>Physical</strong></td>
<td></td>
</tr>
<tr>
<td>Dimensions</td>
<td>9 cm diameter x 3 cm</td>
</tr>
<tr>
<td>Unit Weight</td>
<td>3.5 ounces (100 gms)</td>
</tr>
<tr>
<td><strong>Patient Interface and Safety</strong></td>
<td></td>
</tr>
<tr>
<td>Patient Cable and Lead Wires</td>
<td>Detachable, unshielded, 10 wire cable with defibrillator protection resistance in the snaps</td>
</tr>
<tr>
<td>Input Impedance</td>
<td></td>
</tr>
<tr>
<td>Common Mode Rejection Ratio</td>
<td></td>
</tr>
<tr>
<td>Electrode Offset Tolerance</td>
<td>Meets or exceeds the requirements of ANSI/AAMI EC11</td>
</tr>
<tr>
<td>Input Dynamic Range</td>
<td></td>
</tr>
<tr>
<td>Overload Protection</td>
<td></td>
</tr>
<tr>
<td>Patient Leakage Current</td>
<td>Meets or exceeds the requirements of Class I Type CF Equipment, Standard IEC 60601-1</td>
</tr>
<tr>
<td>Chassis Leakage Current</td>
<td>ANSI/AAMI ES1</td>
</tr>
<tr>
<td><strong>Connectivity</strong></td>
<td></td>
</tr>
<tr>
<td>Standard USB Port</td>
<td>1.1/2.0 Compliant Interface</td>
</tr>
</tbody>
</table>
## Mason Protocol

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Special Features</strong></td>
<td>Off-line ECG viewer and configurable workflow management*, Automated installation via web.</td>
</tr>
<tr>
<td><strong>Waveform Display</strong></td>
<td>Off-line 12-lead ECG viewer</td>
</tr>
</tbody>
</table>
| **Off-line ECG Viewer** | **Speed:** 5 mm/sec, 10 mm/sec, 12.5 mm/sec, 25 mm/sec, 50 mm/sec  
                        | **Gain:** 5 mm/mV, 10 mm/mV, 20 mm/mV  Selectable by user                  |
|                       | **Print out:** Screen snapshot, sliding window based on speed                  |
| **Print Formats**     | Configurable 12 leads by 10 seconds, 25 mm/sec, 10mm/mV                      |
|                       | Default is 4 groups of 3 leads by 2.5 seconds plus  
                        | 1 - 10 second continuous lead II strip at 25 mm/sec, 10 mm/mV              |
| **Filters**           | AC Interference 50/60 Hz                                                     |
|                       | Low pass filters 40, 150 Hz                                                   |
| **ECG Storage**       | **Off-line:** Temporary local storage. Auto upload to database when network connection is established |
|                       | **On-line:** Auto upload to database                                           |

* Spaulding Clinical, LLC will communicate with the Study Sponsor on the details of the ECG services, demographic data input fields, visit information and specifics required to the sites utilizing the Spaulding iQ as outlined by the Study Sponsor.
SITE PC Mason Protocol Software Application

Study Configuration

Review the following minimum SITE PC computer specifications to ensure the correct specifications for the computer hardware and software.

Minimum SITE PC Computer Specifications

<table>
<thead>
<tr>
<th>SITE PC</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Standards</td>
<td>The hardware is compliant with UL and international office equipment</td>
</tr>
<tr>
<td></td>
<td>specifications</td>
</tr>
<tr>
<td>Operating System/</td>
<td>Java Runtime Environment and is compatible with Windows XP,</td>
</tr>
<tr>
<td>Compatibility</td>
<td>Windows Vista and Windows 7 operating systems</td>
</tr>
<tr>
<td>Ram</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>Internet Information</td>
<td>Internet connection for web access to server. Web browser required for</td>
</tr>
<tr>
<td></td>
<td>installation and access to Clinical Information Management System.</td>
</tr>
<tr>
<td>Internet Connection</td>
<td>Provides communication to the Clinical Information Management System (CIMS).</td>
</tr>
<tr>
<td></td>
<td>HTTPS protocols are used to send/receive from CIMS.</td>
</tr>
<tr>
<td>Video Resolution</td>
<td>1024 X 768 (minimum)</td>
</tr>
<tr>
<td>Disk Space</td>
<td>1 GB (minimum)</td>
</tr>
<tr>
<td>USB Port</td>
<td>USB connection available for acquired ECG/Voice data upload from Acquisition</td>
</tr>
<tr>
<td></td>
<td>Module. USB 1.1/2.0 compliant</td>
</tr>
</tbody>
</table>

NOTE: Users of the Mason Protocol software application are recommended to have their computing environment free of viruses and protected from electronic attacks. Contact your computer system administrator to ensure that virus protection software is installed and updated with the latest virus definitions. Before use of the Mason Protocol application and periodically, run a virus scan on the SITE PC computer to ensure that the computing environment is free from viruses and safe for data collection.

SITE PC Mason Protocol Software Installation

Once the study configuration is finalized between the Spaulding Clinical, LLC and the Study Sponsor, the Client Services Representative will provide the study site with a Universal Resource Locator (URL) address, login credentials, and a Spaulding Clinical activation code required to install the SITE PC Mason Protocol software application.

NOTE: Reference the SITE PC Computer Specifications to ensure acceptable hardware configuration.

To install the Mason Protocol software application on the SITE PC computer, follow these steps:
1. Log into the SITE PC computer.
2. Connect to the Internet using a web browser (example, Internet Explorer).
3. Navigate to the URL address provided by the Spaulding Clinical, LLC Client Services Representative.
4. In the Activation Code text box, type in the activation code provided by the Spaulding Clinical, LLC Client Services Representative.

5. Click the Submit button.

6. The iQ Installation Overview window will appear. Click the Launch button located at the bottom of the screen.

7. A Java Web Start window will open and an installation progress bar will show the status of the application as it is downloading to the SITE PC.

8. When the software application has completed the installation progress, the web browser will automatically close and a Spaulding iQ software icon will appear on the desktop.

SITE PC User Identification and Access Permission

Each individual user requires a log in email address and password to access the SITE PC Mason Protocol software application. The Study site’s user identification and password authorization is provided by the Spaulding Clinical, LLC Client Services Representative.

1. Double click the Spaulding iQ icon to launch/open the Mason Protocol software application.

2. The Login window will open.
This section is intended to provide the end user with information about:

- Status Display on the Spaulding iQ ECG Acquisition Module
- Charging the Internal Battery
- Connecting the Patient Cable

### Status Display

The Spaulding iQ ECG Acquisition Module uses a 7-segment LED Display Window on the top side of the device to communicate unique status indicators to user. The meaning and definition of each display code is provided in the following table:
### Status Indicators Used in the 7-segment LED Display Window

<table>
<thead>
<tr>
<th>Display Code</th>
<th>Meaning</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>FULL</td>
<td>Acquisition Module contains voice signature and ECG data. The FULL Acquisition Module must be downloaded to the SITE PC in order to be emptied.</td>
<td></td>
</tr>
<tr>
<td>EMPTY</td>
<td>Acquisition Module does not contain voice signature or ECG data. The EMPTY Acquisition Module is ready to record voice and ECG data.</td>
<td></td>
</tr>
<tr>
<td>LOW BATTERY</td>
<td>Acquisition Module battery capacity too low to begin voice signature or ECG data acquisition. Follow the instructions in the Charging Internal Battery section below to re-charge the internal lithium polymer battery.</td>
<td></td>
</tr>
<tr>
<td>CHARGING</td>
<td>Acquisition Module is charging. C will no longer display when the battery is fully charged.</td>
<td></td>
</tr>
<tr>
<td>RECORDING VOICE</td>
<td>Acquisition Module is currently acquiring voice signature data.</td>
<td></td>
</tr>
<tr>
<td>EXCEEDED VOICE DATA LENGTH</td>
<td>Length of voice signature recording has exceeded 32 seconds. Acquisition Module is no longer recording voice signature data.</td>
<td></td>
</tr>
<tr>
<td>ACQUIRING ECG DATA</td>
<td>Acquisition Module is currently acquiring ECG data.</td>
<td></td>
</tr>
<tr>
<td>ONE HORIZONTAL BAR</td>
<td>Lead quality is poor. ECG Data collected on the Acquisition Module may not provide sufficient data for analysis purposes.</td>
<td></td>
</tr>
<tr>
<td>TWO HORIZONTAL BARS</td>
<td>Lead quality is marginal. ECG Data collected on the Acquisition Module may provide sufficient data for analysis purposes. Check the quality of the ECG data after download.</td>
<td></td>
</tr>
<tr>
<td>THREE HORIZONTAL BARS</td>
<td>Lead quality is acceptable. ECG Data collected on the Acquisition Module is sufficient for data analysis purposes.</td>
<td></td>
</tr>
<tr>
<td>ERASE INDICATOR</td>
<td>Voice signature and ECG data has been transferred to the SITE PC and the Acquisition Module is deleting the data from internal memory.</td>
<td></td>
</tr>
<tr>
<td>UPLOAD MODE</td>
<td>Acquisition Module firmware is being updated by the Mason Protocol.</td>
<td></td>
</tr>
</tbody>
</table>
Charging the Internal Battery

The Spaulding iQ ECG Acquisition Module Internal lithium polymer battery must only be charged by connecting the USB Cable to the USB Cable Port on the Spaulding iQ ECG Acquisition Module and to the SITE PC. Spaulding Clinical, LLC recommends fully charging the Spaulding iQ ECG Acquisition Module before each use.

When "L" (LOW BATTERY) is displayed in the 7-segment LED Display Window, the Spaulding iQ ECG Acquisition Module will not power on and will require immediate charging for a minimum of 20 minutes prior to use.

1. Connect the mini end of the USB Cable to the USB Cable Port on the Spaulding iQ ECG Acquisition Module.
2. Connect the larger end of the USB Cable to the USB Cable Port on the SITE PC.
3. Ensure the USB Cable connecting the Spaulding iQ ECG Acquisition Module and the SITE PC is secure.
4. Ensure the SITE PC is powered on.
5. Allow the Spaulding iQ ECG Acquisition Module to charge for a minimum of 20 minutes.
   **NOTE:** Prior to connecting the Acquisition Module to the SITE PC for charging, inspect the USB cable for damage. Ensure the SITE PC Windows Power Settings are set for continuous power (make certain to disable hibernation or sleep mode on the PC).
   **NOTE:** The letter "C" (CHARGING) or "F" (FULL) will display on the 7-segment LED Display Window while the battery is charging.
   **NOTE:** If completely depleted, the battery requires a complete charge. The charge times could exceed three hours.
6. After 20 minutes has elapsed, disconnect the USB Cable from the USB Cable Ports on the Spaulding iQ ECG Acquisition Module and the SITE PC.
7. If the letter "F" (FULL) is displayed on the 7-segment LED Display Window, follow the steps in the Voice Signal and ECG Data Transfer to SITE PC section to download data from the Spaulding iQ ECG Acquisition Module to the SITE PC.
8. If the letter "E" (EMPTY) is displayed on the 7-segment LED Display Window, follow the steps in the Recording Voice Signature and ECG Data section and begin the data collection process.

**CAUTION:** Use care when connecting the USB cable to the Spaulding iQ ECG Acquisition Module to ensure the appropriate connection is established and that the connector pins are not damaged or bent.
Connecting the Patient Cable to the Spaulding iQ ECG Acquisition Module

1. Follow the steps in Patient Preparation section of this manual to connect the lead wire end of the Patient Cable to the disposable snap-type electrodes affixed to the patient.

2. Connect the Patient Cable to the Spaulding iQ ECG Acquisition Module ECG Cable Port prior to the start of ECG data collection.

NOTE: By design, the Patient Cable only plugs into the ECG Cable Port on the Spaulding iQ ECG Acquisition Module.

⚠️ WARNING: Do not attempt to connect patient cable to any device other than the Acquisition Module.

⚠️ CAUTION: Use care when connecting the Patient Cable to the Spaulding iQ ECG Acquisition Module in order to ensure the appropriate connection is established and that the connector pins are not damaged or bent.
Preparing the Patient

In order for the Spaulding iQ ECG Acquisition Module to achieve the best ECG data quality, take care during patient preparation. A good minimum-impedance pathway will provide superior, noise-free, waveforms. While the study sponsor may designate the style and manufacturer of the electrodes used for ECG acquisition, Spaulding Clinical, LLC recommends wet gel silver-silver chloride (Ag/AgCl) disposable snap electrodes.

⚠️ CAUTION: Electrodes should be stored in an air-tight container. Electrodes will dry out if not stored properly which will cause loss of adhesion and conductivity.

During electrode placement, the patient should be comfortable and completely relaxing in a supine position for a minimum of 5 minutes. To avoid the possibility of muscular tremor, protect the patient from drafts or any other conditions that might cause chills or discomfort.

The patient should also be out of the range of sources of other equipment interference. Equipment interference can be caused by AC power devices or devices which produce high frequency interference such as: portable electronic equipment, microwaves, x-ray equipment. Other interference can be caused by the patient moving or talking.

Electrode Location Preparation

Follow these suggested guidelines when placing the electrodes on the patient:

- Expose the upper arms and upper thighs of the patient to attach the limb leads.
- Place the electrodes on the fleshy part of the arms and legs.
- Clean the electrode sites per skin preparation as discussed below.
- Attach the electrode to the snap end of the lead wires one at a time before applying to the skin.
- Place the electrodes on the inside of each arm (between the shoulder and elbow).
- Place the electrodes slightly on the inside of each thigh (between the hip and knee).
- Place the electrodes at equal distances from the heart (midsternum) and in the same position on each limb.
- For female patients placing an electrode on top of the breast may impede the readings; it should be avoided if possible. It may be necessary to lift the breast and place the electrode underneath in the correct position. Undergarments, such as a bra, must be removed as they can impede readings.
- If a limb site is not available, place the electrodes at an equal distance from the torso, and at an equal distance on the area of the stump.
- To ensure proper adhesion pull slightly on the electrode tab, if the electrode does not move it is adhered to the skin properly. If the electrode moves, it will need to be replaced.

Preparing Patient Skin for ECG Hookup

Skin preparation is important to perform before electrode attachment to help ensure good signal quality when transmitting patient data. Poor skin-electrode contact may cause noise or artifact which can affect the analysis of the ECG data. Low amplitude signals may also be the result of poor skin-electrode contact.

To prepare the skin:

1. Identify the electrode sites on the torso by referring to the Electrode Placement section.
2. Remove any hair from the electrode sites using a razor.
3. Wipe oils from the electrode sites with an alcohol prep pad or warm soapy water.
4. Dry the skin with gauze or a clean, dry towel.

**NOTE:** With elderly or frail patients, take care to not abrade the skin causing discomfort or bruising. Clinical discretion should always be used in patient preparation.
Electrode Placement

Chest Lead Placement

When placing chest leads on the patient, the Angle of Louis is an important biological landmark for determining lead placement. In medical terms, the Angle of Louis is the angle from an articulation of the manubrium and sternum (sternal angle). Use the illustration below as a reference for placement of the precordial (chest/torso) leads. Tactile conformation of this landmark is the first protrusion below the sternal notch, lateral to the second rib which is directly above the 2nd intercostal space.

<table>
<thead>
<tr>
<th>AHA</th>
<th>IEC</th>
<th>Lead Placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1</td>
<td>C1</td>
<td>Fourth intercostal space to the right of the sternum</td>
</tr>
<tr>
<td>V2</td>
<td>C2</td>
<td>Fourth intercostal space to the left of the sternum</td>
</tr>
<tr>
<td>V3</td>
<td>C3</td>
<td>Directly between leads V2 and V4</td>
</tr>
<tr>
<td>V4</td>
<td>C4</td>
<td>Fifth intercostal space at the midclavicular line</td>
</tr>
<tr>
<td>V5</td>
<td>C5</td>
<td>Horizontal with V4 at left anterior axillary line</td>
</tr>
<tr>
<td>V6</td>
<td>C6</td>
<td>Horizontal with V5 at midaxillary line</td>
</tr>
</tbody>
</table>
Proximal Limb Lead Placement

<table>
<thead>
<tr>
<th>AHA</th>
<th>IEC</th>
<th>Lead Placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>RA</td>
<td>R</td>
<td>Right Arm</td>
</tr>
<tr>
<td>LA</td>
<td>L</td>
<td>Left Arm</td>
</tr>
<tr>
<td>RL</td>
<td>N</td>
<td>Right Leg</td>
</tr>
<tr>
<td>LL</td>
<td>F</td>
<td>Left Leg</td>
</tr>
</tbody>
</table>

**Right Arm**: Place the electrode on the inside of the right arm on the fleshy part of the arm between the shoulder and elbow.

**Left Arm**: Place the electrode on the inside of the left arm on the fleshy part of the arm between the shoulder and elbow.

**Right Leg**: Place the electrode slightly on the inside of the right thigh on the fleshy part of the leg between the hip and knee.

**Left Leg**: Place the electrode slightly on the inside of the left thigh on the fleshy part of the leg between the hip and knee.
Lead Wire Color Identification

Each lead wire is identified by color and name. If you are located in the United States, refer to the AHA standard lead colors provided on the left side of the table below. If you are located outside of the United States, refer to the international IEC column, provided on the right side of the table below.

<table>
<thead>
<tr>
<th>AHA</th>
<th>IEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1</td>
<td>Red C1</td>
</tr>
<tr>
<td>V2</td>
<td>Yellow C2</td>
</tr>
<tr>
<td>V3</td>
<td>Green C3</td>
</tr>
<tr>
<td>V4</td>
<td>Blue C4</td>
</tr>
<tr>
<td>V5</td>
<td>Orange C5</td>
</tr>
<tr>
<td>V6</td>
<td>Purple C6</td>
</tr>
<tr>
<td>LA</td>
<td>Yellow L</td>
</tr>
<tr>
<td>RA</td>
<td>Red R</td>
</tr>
<tr>
<td>LL</td>
<td>Green F</td>
</tr>
<tr>
<td>RL</td>
<td>Black N</td>
</tr>
</tbody>
</table>

| LA  | Black Yellow L |
| RA  | Red Red C1   |
| LL  | Green Green C3 |
| RL  | Black Black C6 |

If you are located outside of the United States, refer to the international IEC column, provided on the right side of the table below.
Recording Voice Signature and ECG Data

Within the Mason Protocol software application, voice signature data is analyzed and compared to data stored within the voice data study database. The Mason Protocol software application uses a proprietary method of data analysis to match the voice signature data with the patient information stored in the application and displays the best "match" between voice signature data and demographic information within the software application.

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

Voice Signature Data

1. Position the patient in a supine position in preparation for ECG acquisition.

   ! CAUTION: Excessive patient movement could interfere with the operation of the Spaulding iQ ECG Acquisition Module ECG data collection. Ask the patient to remain still during the ECG data collection period and eliminate additional background noise during the voice recording.

2. Attach the ECG electrodes to the ECG lead wires as instructed in Patient Preparation section.

3. Attach the Patient Cable to the ECG Cable Port on Spaulding iQ ECG Acquisition Module as described in the Connecting the Patient Cable to the Spaulding iQ ECG Acquisition Module section.

4. Press the Main Function button on the Spaulding iQ ECG Acquisition Module one time.

5. Verify the letter "E" (EMPTY) appears on the 7-segment LED Display Window on the Spaulding iQ ECG Acquisition Module.

   NOTE: If the letter “F” (FULL) is displayed on the 7-segment LED Display Window on the Spaulding iQ ECG Acquisition Module, follow the instructions in Signal and ECG Data Transfer to SITE PC section to download data from the Spaulding iQ ECG Acquisition Module to the SITE PC.

   NOTE: If the letter “L” (LOW BATTERY) is displayed on the 7-segment LED Display Window on the Spaulding iQ ECG Acquisition Module, or the Spaulding iQ ECG Acquisition Module does not respond, follow the instructions in the Charging the Internal Battery section.

6. Position the Spaulding iQ ECG Acquisition Module, with the microphone for voice detection, between 8-12 inches from the patient’s face.
7. Press and hold the *Main Function* button on the Spaulding iQ ECG Acquisition Module while the patient reads the script. The letter “r” (RECORDING VOICE) will display in the 7-segment LED Display Window while the Spaulding iQ ECG Acquisition Module records the voice data.

**NOTE:** The Spaulding iQ ECG Acquisition Module will record up to 30 seconds of voice data during the voice signature data recording process. The patient must record a minimum of 10 seconds of voice data.

**NOTE:** If the letter “r” displayed in the 7-segment LED Display Window begins to blink, the data recording has exceeded 32 seconds in length. This means the Spaulding iQ ECG Acquisition Module has collected a sufficient amount of voice data required for voice signature data analysis within the Mason Protocol software application.

---

**Voice Recording Example Script**

1. During voice signature data recording, ensure no one is speaking except the patient. Instruct the patient to slowly and clearly read a script similar to the *Voice Recording Example Script* provided below.

   **My name is:**
   **My initials are:**
   **My date of birth is:**
   **My gender is:**
   **The Sponsor of this study is:**
   **The Protocol number is:**
   **The Visit Identifier is:**
   **I am participating in a research study. My voice is being recorded for the study identification.**

   **NOTE:** The information captured in the voice data recording will be study- or protocol-specific and the voice recording script is subject to change.

2. When the patient has finished reading the script, release the *Main Function* button. Move immediately to the ECG data collection process described in the *ECG Data* section.

   **NOTE:** ECG data collection must begin on the Spaulding iQ ECG Acquisition Module within 4 minutes of acquiring voice signature data. If a time period greater than 4 minutes have elapsed between voice and data collection, the Spaulding iQ ECG Acquisition Module will automatically delete the patient’s voice data and the voice signature data process must be repeated.
Re-Record Voice Signature Data

Depending on the audio quality or content of the recording, patient voice signature data may be deleted and re-recorded before it is downloaded to the SITE PC. Voice signature data re-recording must be accomplished before the ECG data collection process begins.

1. To erase the voice data from the Acquisition module, press and hold the Main Function button on the Spaulding iQ ECG Acquisition Module for approximately two seconds.
   
   **NOTE:** the Erase Indicator will appear on the 7-segment LED Display Window while the voice data is erased from the Spaulding iQ Acquisition Module.

2. Verify the letter "E" (EMPTY) re-appears on the 7-segment LED Display.

3. Follow the steps in the Voice Signature Data section and repeat the voice signature data recording process.
   
   When voice data is successfully recorded move on to collecting ECG Data.

ECG Data

1. Verify the patient is connected to the Spaulding iQ Acquisition Module and voice data has been recorded.

2. With the patient in a supine position, instruct the patient to remain still for up to a 5 minute session of ECG data recording.
   
   **NOTE:** A minimum of 1 minute of ECG data collection is required for data analysis.

3. To verify lead quality, assure all horizontal bars are displayed.

   **ONE HORIZONTAL BAR**
   
   Lead quality is poor. ECG Data collected on the Acquisition Module may not provide sufficient data for analysis purposes.

   **TWO HORIZONTAL BARS**
   
   Lead quality is marginal. ECG Data collected on the Acquisition Module may provide sufficient data for analysis purposes. Check the quality of the ECG data after download.

   **THREE HORIZONTAL BARS**
   
   Lead quality is acceptable. ECG Data collected on the Acquisition Module is sufficient for data analysis purposes.

4. Once lead quality is acceptable for recording, press the Main Function button to begin recording the ECG.
   
   **NOTE:** While the Spaulding iQ Acquisition Module is collecting ECG data, "A" (ACQUIRING ECG DATA) will appear in the 7-segment LED Display Window.

5. After 5 minutes of ECG data recording, depress the Main Function button to stop recording data or the ECG data collection will automatically stop if collection exceeds 5 minutes.

6. Disconnect the patient cable from the Spaulding iQ ECG Acquisition Module. Ask the patient remain connected to the patient cable and electrodes until verification of a good quality ECG is downloaded to the SITE PC.
Voice Signal and ECG Data Transfer to SITE PC

This section describes the steps required to transfer voice signal and ECG data from the Spaulding iQ ECG Acquisition Module to the SITE PC using the Mason Protocol software application.

**NOTE:** Voice signal and ECG data can only be uploaded to the CIMS by authorized users. User credentials are verified by the Mason Protocol software against the sponsor, protocol, and user database. Unauthorized users will not be granted access to the Mason Protocol software application.

1. If necessary, log into the SITE PC computer.
2. Connect the larger end of the USB Cable to the USB Cable Port on the SITE PC. Connect the small end of the USB cable to the Acquisition Module, see illustrations below.
3. Double click the Spaulding iQ software icon to launch/open the Mason Protocol software application.

4. In the Login window, log into the Mason Protocol software application with the user credentials provided by the Spaulding Clinical, LLC Client Services Representative.

5. When the Spaulding iQ ECG Acquisition Module is automatically detected by the SITE PC Mason Protocol software application, the Device Data Summary window will appear.

6. Voice and ECG Progress bars will show the status of voice signature and ECG data transfer from the Spaulding iQ Acquisition Module to the SITE PC. When both progress bars have reached 100% the Device Data Summary window will close and the Assign Demographics window will appear.
7. Once the Mason Protocol software application has processed the voice signature data (using a proprietary method of data analysis to match the voice signature data with the patient/subject information stored in the application), an Assign Demographics window will appear with the demographic information of the patient best “matched” with the existing voice signature data in the system.

8. Verify the patient information is accurate by clicking the Play Voice button if audio verification is necessary.

New Patient Enrollment

NOTE: If the patient/subject is not in the study database (for example, during an initial study visit) a voice match will not exist within the Mason Protocol software application.

1. To add a new patient/subject to the Mason Protocol software application, click the Add New Subject button in the Assign Demographics window. The Add Subject (patient) window will appear.
2. Enter patient demographics into the respective fields.

**NOTE:** This illustration is for reference only, the data fields are configurable on a study by study basis.

**NOTE:** Enter data into the applicable fields in the Add Subject (patient) window in order for the patient to be added to the study database.

**NOTE:** Patient demographic data cannot be changed once the Add Subject (patient) window is closed. Modification to this information is allowed only through the use of the query process.

3. Click the **Save Subject** button. The Visit Confirmation window will appear.

4. Select the appropriate patient visit from the drop down menu.

   **NOTE:** By default, the Mason Protocol software application numerically and incrementally increases the site visit number for each visit (Visit 1, Visit 2, and so on).

5. Click the **Associate Visit** button.

6. The transfer of new patient ECG data will automatically occur between the SITE PC and the CIMS and the Visit Designation window will automatically close.

   **NOTE:** At this point, voice signature and ECG data stored on the Spaulding iQ Acquisition Module is deleted from the Acquisition Module. The erase indicator symbol will display on the Acquisition Module LED display as the data is deleted.

7. When the data has completely transferred from the SITE PC to the CIMS, the Download ECG window will open. At this point, a PDF file containing an unconfirmed ECG report is available for viewing. The PDF file may automatically open for viewing, or the user may manually open the file by clicking the Download ECG link.
View ECG

As a means of allowing the clinician to check the quality of ECG data, ECG data may be reviewed in the PDF file provided in the Download ECG Window.

The clinician can print the ECG in two landscape formats:
- Off-line Mode: 12 leads by 10 seconds, 25 mm/s, 10mm/mV with Patient ID
- On-line Mode: 4 groups of 3 leads by 2.5 seconds and a 10 second continuous lead II strip at 25 mm/sec, 10 mm/mV with Patient ID
Return Patient/Follow Up Visit

Voice Pairing Confirmation
1. If the subject voice pairing within the SITE PC is strong, the Assign Demographics window will open and display the patient’s analysis information at the top of the window.
   **NOTE:** Patient match is listed in descending order in the Assign Demographics window, with the highest probable match at the top of the list.

2. Select the row containing the correct patient demographics and double click with the mouse or keypad. The Selection Confirmation window will open.

3. Click Yes to confirm or click No to select a different patient.
4. The Visit Confirmation window will appear.

5. Select the appropriate patient visit from the drop down menu.
   **NOTE:** By default, the Mason Protocol software application numerically and incrementally increases the site visit number for each visit (Visit 1, Visit 2, and so on).
   **NOTE:** An unscheduled visit may also be assigned by selecting “unscheduled” from the bottom of the list.
6. Click the Associate Visit button.
7. The transfer of ECG data will automatically occur between the SITE PC and the CIMS and the Visit Designation window will automatically close.

**NOTE:** At this point, voice signature and ECG data stored on the Spaulding iQ Acquisition Module is deleted from the Acquisition Module. The erase indicator symbol will display on the Acquisition Module LED display as the data is deleted.

8. When the data has completely transferred from the SITE PC to the CIMS, the Download ECG window will open. At this point, a PDF file containing an unconfirmed ECG report is available for viewing. The PDF file may automatically open for viewing, or the user may manually open the file by clicking the Download ECG link.

### Spaulding Clinical ECG Report

#### Study / Subject Data
- **Acquisition Time:** 31Oct2011 14:15:41
- **Subject:** 12345
- **Age:** 37
- **Gender:** Male
- **1007 Thomas Walthers, MD**

#### Average Measurements
- **HR:** 62
- **QT:** 412
- **QTcF:** 415
- **QRS:** 100
- **PR:** 200
- **RR:** 972

#### Interpretations
- Sinus rhythm
- Normal ECG
- **UNCONFIRMED REPORT**

---

**EKG Report**

Printed on Monday, October 31, 2011 14:20:16 by CalECG version 3.1.0 - Amps llc (www.amps-llc.com)
Off-line Workflow

In the event the internet connection is lost, the workflow at the SITE PC will be the same as in the on-line mode with the following exceptions:

- Voice signature data association will be bypassed and the authorized user must manually select the patient with the correct demographic entry.
- The voice signal and ECG data is downloaded from the Spaulding iQ ECG Acquisition Module and remains on the SITE PC until the internet connection is re-established and the Mason Protocol software application is launched.
- ECG data review and printing is available for ECG quality check, then stored to the SITE PC until internet connection is re-established.

1. Follow the steps in the Voice Signal and ECG Data Transfer to SITE PC section to add data to a new or existing patient.
2. In Off-line Mode, the patient list in the Assign Demographics window is displayed by patient ID, with no voice scoring.
3. Click Add New Patient and follow the steps in the New Patient Enrollment section to add a new patient.

OR

4. Select the row containing the correct patient demographics and double click with the mouse or keypad to add a new visit for an existing patient.
5. The following error message will appear in the ECG Transmission window: ECG transmission failed, please check your internet connection. To postpone the upload attempt, click the button below.

6. To proceed in the off-line workflow click the View ECG button to launch the off-line ECG viewer.
7. The Loading ECG progress bar will appear followed by the printable 12 lead ECG display interface for the purpose of ECG lead quality check.

8. After reviewing ECG for lead quality, select the "X" in the upper right corner of the window to close the ECG off-line viewer.

9. The message window will open requiring confirmation. Select "Yes", the ECG data is stored to the SITE PC until Internet connection is re-established.

NOTE: When the internet connection is re-established and the Mason Protocol is opened, an automatic transfer of voice and ECG data from the SITE PC to the CIMS will occur.
 Troubleshooting

This section is intended to provide the user suggested maintenance and troubleshooting suggestions.

## LED Display Code Troubleshooting

<table>
<thead>
<tr>
<th>Behavior or LED display code</th>
<th>Probable Cause</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low Battery “L”</strong></td>
<td>Battery is LOW</td>
<td>Follow the steps found in <em>Charging the internal Battery</em> section of the manual</td>
</tr>
<tr>
<td><strong>No display</strong></td>
<td>Battery depleted</td>
<td>Follow the steps found in <em>Charging the internal Battery</em> section of the manual. Repeat process until a display code appears in the 7-segment LED Display Window.</td>
</tr>
<tr>
<td><strong>FULL “F”</strong></td>
<td>Acquisition Module contains voice and ECG data. Additional data cannot be recorded.</td>
<td>Follow the steps in <em>Voice Signal and ECG Data Transfer to SITE PC</em> section of the manual.</td>
</tr>
<tr>
<td><strong>Frozen in UPLOAD MODE “U”</strong></td>
<td>Spaulding iQ Acquisition module is locked in firmware upload mode.</td>
<td>Call Spaulding Client Services</td>
</tr>
</tbody>
</table>
| **1 BAR**                   | Lead quality is poor. | ▪ Follow the instruction in the Patient Preparation, Electrode Location Preparation, Preparing Patient Skin for ECG Hookup, Electrode Placement and/or Equipment Preparation sections of the Manual.  
                              ▪ Inspect your equipment, verify the integrity of the leads and make sure all leads are connected. |
| **2 BAR**                   | Lead quality is marginal. | ▪ Follow the instruction in the Patient Preparation, Electrode Location Preparation, Preparing Patient Skin for ECG Hookup, Electrode Placement and/or Equipment Preparation sections of the Manual.  
                              ▪ Inspect your equipment, verify the integrity of the leads and make sure all leads are connected. |
Voice Signature Data Troubleshooting

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Probable Cause</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor Biometric or Voice Signature data match cannot be established.</td>
<td>Poor voice quality due to:  ■ No voice collected  ■ Acquisition module too far from patient during recording  ■ Patient voice recording too quiet  ■ Too much background noise during recording</td>
<td>Follow the steps in Recording Voice Signature and ECG Data section of the manual.</td>
</tr>
<tr>
<td>Voice Signature Data is erased</td>
<td>Inactivity time-out after recording voice exceeds 4 minutes causes the Acquisition Module to erase</td>
<td>Follow the steps in Recording Voice Signature and ECG Data section of the manual.</td>
</tr>
</tbody>
</table>

ECG Data Troubleshooting Chart

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Probable Cause</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor Quality ECG displayed in the pdf rendering</td>
<td>Poor electrode placement and connectivity to the patient.  ECG may contain excessive artifact interrupting further processing.</td>
<td>Follow the steps in Recording Voice Signature and ECG Data section of the manual and repeat the voice and ECG data collection and download process.</td>
</tr>
</tbody>
</table>

Troubleshooting the SITE PC

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Probable Cause</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error message: &quot;ECG transmission failed, Please check internet connection&quot; To postpone the upload attempt, click the button below.</td>
<td>Loss of internet connection</td>
<td>Follow the steps in &quot;Off-line Workflow&quot; section of the manual.  Check the internet connection. Call your internal IT Support Group and Spaulding Client Services.</td>
</tr>
<tr>
<td>Error Message ECG cannot be processed – Spaulding Clinical is investigating.</td>
<td>Insufficient ECG data, collected less than recommended.</td>
<td>Follow the steps in Recording Voice Signature and ECG Data section of the manual for instructions to recollect the ECG data.</td>
</tr>
</tbody>
</table>

Password Login Errors

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Probable Cause</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Login error</td>
<td>Incorrect password credentials</td>
<td>Call Spaulding Client Services</td>
</tr>
</tbody>
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