Contact Information

Headquarters
Spaulding Clinical, LLC
525 South Silverbrook Drive
West Bend, Wisconsin 53095
USA
Tel: 262.334.6020
Fax: 262.334.6067
Internet: www.spauldingclinical.com

European Union Representative
Wellkang Ltd
Suite B, 29 Harley Street
LONDON, W1G 9QR
UK
Tel: +44(20) 32876300
Fax: +44(20)76811874
Email 1: AuthRep@CE-marking.eu (shared & preferred for receiving emails)
Email 2: AuthRep@CE-marking.com (shared)

Sales Support/Supplies & Accessories
Spaulding Clinical, LLC
525 South Silverbrook Drive
West Bend, Wisconsin 53095
USA
Tel: 262.306.3348  Client Services
Tel: 262.334.6020
Fax: 262.334.6067
Email: info@spauldingclinical.com

Client Services & Technical Support Group
Spaulding Clinical, LLC
525 South Silverbrook Drive
West Bend, Wisconsin 53095
USA
Tel: 1-888-607-7871
Tel: 262.306.3348
Tel: 262.334.6020
Fax: 262.334.6067
Email: clientservices@spauldingclinical.com

This document contains confidential information that belongs to Spaulding Clinical, LLC. No part of this document may be copied, transmitted, used, or disclosed outside of the intended recipient without the written approval of Spaulding Clinical, LLC.

NOTE: Microsoft and Windows brand operating systems are registered trademarks of Microsoft Corporation in the United States and other countries.
Contents

System Information

Introduction .............................................................................................................................................. 1
  User Manual Purpose ............................................................................................................................ 1
  System Description ............................................................................................................................... 1
  Purpose ................................................................................................................................................ 1
  Intended Users ..................................................................................................................................... 2
  Indications for Use .............................................................................................................................. 2
  Patient Population .............................................................................................................................. 2
  Environment ....................................................................................................................................... 2
  Methods and Frequency of Use .......................................................................................................... 2

Notifications ........................................................................................................................................ 3
  Manufacturer’s Responsibility ................................................................................................................ 3
  Responsibility of the End User ............................................................................................................. 3
  Spaulding iQ Electrocardiograph Acquisition Module Serial Number Identification ......................... 3
  Copyright and Trademark Notices ...................................................................................................... 3
  Other Important Information .............................................................................................................. 3

Equipment Symbols and Markings .................................................................................................... 5

User Safety Information ..................................................................................................................... 6

WARNINGS ............................................................................................................................................ 6

CAUTIONS ............................................................................................................................................ 8

NOTES ..................................................................................................................................................... 8

Electromagnetic Compatibility ........................................................................................................... 10

General Care and Cleaning Instructions ............................................................................................ 14
  General Care ....................................................................................................................................... 14
  Cleaning the Patient Cable and the Acquisition Module ..................................................................... 14
  Methods .............................................................................................................................................. 14

System Description ............................................................................................................................. 15

Spaulding iQ ECG Acquisition Module ............................................................................................... 16
  Spaulding iQ ECG Acquisition Module Specifications ........................................................................ 17
  Mason Protocol ................................................................................................................................. 18

Software Installation & Equipment Preparation

Computing Device Mason Protocol Software Application .................................................................... 19
  Site Configuration ............................................................................................................................... 19
  Minimum Computing Device Specifications ....................................................................................... 19
  Computing Device Mason Protocol Software Installation ................................................................ 19
  Computing Device User Identification and Access Permission ....................................................... 20

Equipment Preparation ....................................................................................................................... 21
  Status Window.................................................................................................................................. 21
  Verify Lead Quality ............................................................................................................................ 22
  Charging the Internal Battery ............................................................................................................. 23
  Charging the Battery via Computing Device ....................................................................................... 23
  Connecting the Patient Cable to the Spaulding iQ ECG Acquisition Module ..................................... 24
Contents

Patient Preparation

Preparing the Patient ................................................................. 25
Preparation of Patient Skin for ECG Hookup ................................. 25
Electrode Location Preparation .................................................... 25

Electrode Placement ................................................................. 26
AHA Lead Placement ..................................................................... 26
IEC Lead Placement ..................................................................... 27
Leadwire Color Identification ........................................................ 28

Data Collection & Transfer

Linking Voice Signature Data to Patient Demographics ................. 29
Voice Signature Data ..................................................................... 29
Re-record Voice Signature Data .................................................... 31
ECG Data .................................................................................... 32

Voice Signal and ECG Data Transfer to Computing Device .......... 33
New Patient Enrollment ............................................................... 35
View ECG .................................................................................. 37
Return Patient/Follow Up Visit ................................................... 38

Off-line Workflow ....................................................................... 40

Maintenance & Troubleshooting

Troubleshooting ........................................................................ 43
LED Status Window Display Code Troubleshooting ....................... 43
Voice Signature Data Troubleshooting .......................................... 44
ECG Data Troubleshooting Chart .................................................. 44
Troubleshooting the Computing Device ........................................ 44
Password Login Errors .................................................................. 44
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 Computing Device
- 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 Computing Device located at the participating site, installed with the Mason Protocol, a proprietary Spaulding Clinical, LLC software application that receives ECG and (optional) voice 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 and (optional) voice data.

The complete Spaulding iQ Electrocardiograph System includes the Spaulding iQ ECG Acquisition Module with the Spaulding iQ 12-lead Patient Cable, USB Cable, and the Computing Device with the Mason Protocol software application. The Computing Device software may be installed on an office Computing Device 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 healthcare procedures or clinical research protocols and to transmit the ECG data to the participating Computing Device and CIMS.
Intended Users
The Spaulding iQ Electrocardiograph System is intended to be used by qualified medical professionals or trained personnel under the guidance/order of 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 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.

Methods and Frequency of Use
The Spaulding iQ Electrocardiograph System is intended for use by a physician’s order or at a frequency defined within research protocols.

A supplied Spaulding iQ 12-lead Patient Cable connects to the patient with disposable snap-type electrodes [short term Ag/AgCl] applied to the thorax and limbs, and connects 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 within 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.
Limited Warranty

Spaulding Clinical Research, LLC hereby warrants that Spaulding Clinical Research, LLC products (hereinafter referred to as “Product/s”) shall be free from defects in material and workmanship under normal use, service, and maintenance for the warranty period of such Product/s from Spaulding Clinical Research, LLC or an authorized distributor or representative of Spaulding Clinical Research, LLC. The warranty period is defined as twelve (12) months following the date Product is received from Spaulding Clinical Research, LLC (not to exceed 13 months from the date of shipment from Spaulding Clinical Research, LLC). Normal use, service, and maintenance mean operation and maintenance in accordance with appropriate instructions and/or information guides. This warranty does not apply to damage to the Product/s caused by any or all of the following circumstances or conditions:

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>
| EC REP  | Wellkang Ltd  
Suite B, 29 Harley Street  
London, W1G 9QR, U.K. |
| Spaulding Clinical, LLC  
525 South Silverbrook Drive  
West Bend, Wisconsin 53095  
USA |
| CE Marking | 0086 |
User Safety Information

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.

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

**WARNINGS**

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 under the guidance/order of 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 ECG Acquisition 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. The ECG Acquisition Module, however, may be used on patients with an implantable defibrillator. The ECG Acquisition Module provides defibrillation protection only when used with a Spaulding iQ 12-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 resistors (9K ohm minimum) in each lead for defibrillation protection. Patient cables should be checked for cracks, breakage, or damage of any kind prior to use. Do not use damaged cables, devices, or accessories.
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, the Spaulding iQ ECG Acquisition Module, Patient Cables,
and leadwires 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.

A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture
with air, with oxygen or with 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 Spaulding iQ ECG 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 that can come in direct
patient contact must be in compliance with UL 60601-1, IEC 60601-1, IEC 60601-1-11, and IEC 60601-2-25. Only use
equipment and accessories supplied with the device or specified/approved for use by, Spaulding Clinical LLC.

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

Set the computing device to the correct date/time prior to use with the Spaulding iQ ECG Acquisition Module.

User should run regular virus checks on all Computing Devices that are used with the Spaulding iQ ECG
Acquisition Module to ensure safe/effective operation.

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

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.

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

The Spaulding iQ Electrocardiograph System 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.

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.

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

Computing Device display settings must accommodate local lighting conditions for readability.

To avoid the possibility of the wireless device interfering with other emergency equipment (e.g. cell phones), test
the function in advance to assure compatibility.

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.
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.

⚠️ 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 Computing Device 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 and accessories.

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

The Spaulding iQ ECG 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, loss of conductivity, and poor quality ECG data.

Use care when connecting the Patient Cable and 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.

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

The Spaulding iQ ECG Acquisition Module is intended to be used in a controlled environment, and should be used and stored according to the published environmental specifications.

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

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.
<table>
<thead>
<tr>
<th>Excessive patient movement could interfere with the operation of the Spaulding iQ ECG Acquisition Module’s ECG data collection. Ask the patient to remain still during the ECG data collection period.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper patient skin preparation is important to correct application of ECG electrodes and operation of the device.</td>
</tr>
<tr>
<td>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 Computing Device to charge (&quot;C&quot;) the battery.</td>
</tr>
<tr>
<td>The Spaulding iQ ECG Acquisition Module is distributed ready to use. No further assembly is required by the end user.</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

---

**Medical Equipment**

With respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1, and IEC 60601-2-25.

This device is UL Classified.

---

**CE Marking**

0086
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 12-lead Patient Cable AHA</td>
<td>WR0458CS</td>
</tr>
<tr>
<td>Spaulding iQ 12-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 CISPR 11</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>RF Emissions CISPR 11</td>
<td>Class B</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>Harmonic Emissions IEC 61000-3-2</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations/Flicker Emissions IEC 61000-3-3</td>
<td>Not Applicable</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</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment: Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV contact</td>
<td>± 6 kV contact</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>± 8 kV air</td>
<td>± 8 kV air</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>Participating Computing Device must meet the criteria under IEC 60950</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>Participating Computing Device must meet the criteria under IEC 60950</td>
<td></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 Computing Device 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>
<tr>
<td></td>
<td></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>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
</table>
| Conducted RF   | 3 Vrms                | 3 Vrms           | 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. Recommended separation distance:  

\[
d = \sqrt{\frac{3.5}{V_{rms}}} V_P
\]

\[
d = \sqrt{\frac{7}{3V/m}} V_P
\]

Where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and \( d \) is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range†. Interference may occur in the vicinity of equipment marked with the following symbol:

\[
\text{Radiated RF}  
\]

\[
\text{IEC 61000-4-3} 
\]

3 V/m  3 V/m  80 MHz to 2.5 GHz

80 MHz to

2.5 GHz

* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, ECG Acquisition Module 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 \sqrt{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>
</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 ECG Acquisition Module for any visible damage.
- Inspect the Patient Cable and connectors for any visible damage.
- Inspect the Main Function button and LED Status Window for proper function and appearance.
- The ECG Acquisition Module has no serviceable parts and calibration is not required. Periodically check functionality of the ECG Acquisition Module by performing a test ECG and (optional) Voice acquisition and observing the expected results using a non-patient visit designator (e.g. “TEST”).

Cleaning the Patient Cable and the ECG 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.

⚠️ WARNING: To avoid potential for spread of disease or infection, the Spaulding iQ ECG Acquisition Module, Patient Cables, and leadwires 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.

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

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 ECG Acquisition Module, the Patient Cable, and leadwires, use a dry, lint-free, soft cloth that is slightly moistened with a mild detergent and warm water solution. Wipe the equipment exterior surfaces and cables with a dry, lint-free, soft cloth and let them air dry. Do not use any excessive drying techniques, such as forced heat.
- Do not spray any cleaning solution directly onto the ECG Acquisition Module. Do not autoclave the Patient Cable or ECG Acquisition Module.
- Do not attempt to clean the device or patient cables by submerging into any liquid, autoclave, or steam cleaning as this may damage the Spaulding iQ ECG Acquisition Module and accessories.
- Never expose the 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>
<tbody>
<tr>
<td>Spaulding iQ ECG Acquisition Module Kit</td>
<td>KT-1020973-AHA</td>
</tr>
<tr>
<td></td>
<td>KT-1020973-IEC</td>
</tr>
<tr>
<td>Spaulding iQ 12-lead Patient Cable</td>
<td>AHA: WR0458CS</td>
</tr>
<tr>
<td></td>
<td>IEC: WR0459CS</td>
</tr>
<tr>
<td>USB Cable</td>
<td>WR0457CS</td>
</tr>
<tr>
<td>Disposable snap-type electrodes</td>
<td>Call Spaulding Client Services &amp; Technical Support Group 1-888-607-7871 to reorder electrodes</td>
</tr>
<tr>
<td>User Manual</td>
<td>9920-101-02-eng</td>
</tr>
<tr>
<td>Spaulding iQ Electrocardiograph System Computing Device Installation and Start Up Instructions</td>
<td>9920-101-04-eng</td>
</tr>
<tr>
<td>CD Label and Assembly</td>
<td>9920-101-07-eng</td>
</tr>
</tbody>
</table>
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><strong>Device Classification Specification</strong></td>
<td>Class I, type CF Defibrillation-proof applied parts</td>
</tr>
<tr>
<td><strong>Instrument Type</strong></td>
<td>12-lead Electrocardiograph</td>
</tr>
<tr>
<td><strong>Input Channels</strong></td>
<td>5-minute, simultaneous acquisition of all 12-leads</td>
</tr>
<tr>
<td></td>
<td>30-second voice signal recording</td>
</tr>
<tr>
<td><strong>Standard Leads Acquired</strong></td>
<td>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6</td>
</tr>
<tr>
<td><strong>Storage Capacity</strong></td>
<td>Up to 30-seconds voice signal and 5-minutes ECG data</td>
</tr>
<tr>
<td><strong>Operator Message Display</strong></td>
<td>LED Status Window</td>
</tr>
<tr>
<td><strong>Operator Interface Controls</strong></td>
<td>Front panel touch button</td>
</tr>
<tr>
<td><strong>A/D Conversion</strong></td>
<td>12 bits (2.664 microvolt LSB)</td>
</tr>
<tr>
<td><strong>Digital Sampling Rate</strong></td>
<td>1000 s/sec/channel</td>
</tr>
<tr>
<td><strong>Frequency Response</strong></td>
<td>0.05 to 150 Hz</td>
</tr>
<tr>
<td><strong>Special Functions</strong></td>
<td>Integrated Lead Quality Check, High performance baseline recovery</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Battery Type</strong></td>
<td>Internal rechargeable lithium polymer battery</td>
</tr>
<tr>
<td><strong>Sleep Mode</strong></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><strong>Dimensions</strong></td>
<td>3.5 in. diameter x 1 in. (9 cm diameter x 3 cm)</td>
</tr>
<tr>
<td><strong>Unit Weight</strong></td>
<td>3.5 ounces (100 gms)</td>
</tr>
<tr>
<td><strong>Patient Interface and Safety</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Patient Cable and Leadwires</strong></td>
<td>Detachable, unshielded, 10 leadwire cable with defibrillator protection resistance in the snaps</td>
</tr>
<tr>
<td><strong>Input Impedance</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Common Mode Rejection Ratio</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Electrode Offset Tolerance</strong></td>
<td>Meets or exceeds the requirements of ANSI/AAMI EC11</td>
</tr>
<tr>
<td><strong>Input Dynamic Range</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Overload Protection</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Patient Leakage Current</strong></td>
<td>Meets or exceeds the requirements of Class I Type CF Equipment, Standard IEC 60601-1</td>
</tr>
<tr>
<td><strong>Chassis Leakage Current</strong></td>
<td>ANSI/AAMI ES1</td>
</tr>
<tr>
<td><strong>Connectivity</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Standard USB Port</strong></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, 10 mm/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 Client on the details of the ECG services, demographic data input fields and ECG Report formats.
Computing Device Mason Protocol Software Application

Site Configuration

Review the following minimum Computing Device specifications to ensure the correct specifications for the Computing Device hardware and software.

Minimum Computing Device Specifications

<table>
<thead>
<tr>
<th>Computing Device</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 (CIMS).</td>
</tr>
<tr>
<td>Internet Connection</td>
<td>Provides communication to the Clinical Information Management System</td>
</tr>
<tr>
<td></td>
<td>(CIMS). 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 Acquition</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 Computing Device 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 Computing Device to ensure that the computing environment is free from viruses and safe for data collection.

Computing Device Mason Protocol Software Installation

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

NOTE: Reference the Computing Device Specifications to ensure acceptable hardware configuration.

To install the Mason Protocol software application on the Computing Device, follow these steps:

1. Log into the Computing Device.
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. **NOTE:** This is a one-time process.

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 Computing Device.

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.

**Computing Device User Identification and Access Permission**

Each individual user requires a login email address and password to access the Computing Device Mason Protocol software application. The 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.
3. Enter login credentials.
Equipment Preparation

This section is intended to provide the end user with information about:

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

Status Window

The Spaulding iQ ECG Acquisition Module uses a LED Status 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:
Verify Lead Quality

To verify lead quality, assure three horizontal bars are displayed in the module’s LED Status Window; or that no “lead-fail” message is displayed on the Computing Device.

<table>
<thead>
<tr>
<th>Display Code</th>
<th>Meaning</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMPTY</td>
<td>ECG Acquisition Module does not contain voice or ECG data and is ready to record ECG and (optional) voice data.</td>
<td></td>
</tr>
<tr>
<td>RECORDING VOICE</td>
<td>ECG Acquisition Module is currently acquiring voice data.</td>
<td></td>
</tr>
<tr>
<td>ONE HORIZONTAL BAR</td>
<td>ECG signal quality is poor. ECG Data that will be collected by the ECG Acquisition Module may not provide sufficient data for analysis purposes. It is recommended that the patient be prepped and new electrodes be applied.</td>
<td></td>
</tr>
<tr>
<td>TWO HORIZONTAL BARS</td>
<td>ECG signal quality is marginal. ECG Data that will be collected by the ECG Acquisition Module may provide sufficient data for analysis purposes. Check the quality of the ECG data after upload. It is recommended that the patient be prepped and new electrodes be applied.</td>
<td></td>
</tr>
<tr>
<td>THREE HORIZONTAL BARS</td>
<td>ECG signal quality is excellent. ECG Data that will be collected by the ECG Acquisition Module is sufficient for data analysis purposes.</td>
<td></td>
</tr>
<tr>
<td>ACQUIRING ECG DATA</td>
<td>ECG Acquisition Module is currently acquiring ECG data.</td>
<td></td>
</tr>
<tr>
<td>FULL</td>
<td>ECG Acquisition Module contains ECG and (optional) voice signature data. The FULL ECG Acquisition Module must be downloaded to the Computing Device in order to be emptied/readied for a new data acquisition.</td>
<td></td>
</tr>
<tr>
<td>ERASE INDICATOR</td>
<td>Voice signature and ECG data have been transferred to the Computing Device and the ECG Acquisition Module is deleting the data from internal memory.</td>
<td></td>
</tr>
<tr>
<td>CHARGING</td>
<td>ECG Acquisition Module is charging. The letter “C” (CHARGING) will no longer display when the battery is fully charged.</td>
<td></td>
</tr>
<tr>
<td>LOW BATTERY</td>
<td>ECG Acquisition Module battery capacity is too low to begin voice or ECG data acquisition. Follow the instructions in the Charging the Internal Battery section below to re-charge the internal battery.</td>
<td></td>
</tr>
<tr>
<td>UPLOAD MODE</td>
<td>ECG Acquisition Module firmware is being updated by the Mason Protocol.</td>
<td></td>
</tr>
<tr>
<td>EXCEEDED VOICE DATA LENGTH</td>
<td>Length of voice recording has exceeded 30 seconds. ECG Acquisition Module is no longer recording voice data. No user action required.</td>
<td></td>
</tr>
</tbody>
</table>

Blinking
Charging the Internal Battery

The Spaulding iQ ECG Acquisition Module Internal lithium polymer rechargeable 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 Computing Device, or by using a Spaulding Clinical approved charger. Spaulding Clinical, LLC recommends fully charging the Spaulding iQ ECG Acquisition Module before each use.

When “L” (LOW BATTERY) is displayed in the LED Status 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.

Charging the Battery via Computing Device

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 Computing Device.
3. Ensure the USB Cable connecting the Spaulding iQ ECG Acquisition Module and the Computing Device is secure.
4. Ensure the Computing Device 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 Computing Device for charging, inspect the USB cable for damage. Ensure the Computing Device Windows Power Settings are set for continuous power (make certain to disable hibernation or sleep mode on the Computing Device).

   NOTE: The letter “C” (CHARGING) or “F” (FULL) will display on the LED Status 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 Computing Device.
7. If the letter “F” (FULL) is displayed on the LED Status Window, follow the steps in the Voice Signal and ECG Data Transfer to Computing Device section to download data from the Spaulding iQ ECG Acquisition Module to the Computing Device.
8. If the letter “E” (EMPTY) is displayed on the LED Status 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 leadwire end of the Patient Cable to the disposable snap-type electrodes and affix the electrodes to the patient.

2. Connect the molded connector end of the Patient Cable to the Spaulding iQ ECG Acquisition Module’s 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 the Patient Cable to any device other than the Spaulding iQ ECG Acquisition Module.

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

In order for the Spaulding iQ 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 client 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 type 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, and x-ray equipment. Other interference can be caused by the patient moving or talking.

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 quality and 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 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.
- Verify that electrodes are within the expiration date. Do not use any disposable supplies that are beyond their expiration date.
- Place the electrodes on the fleshy part of the arms and legs.
- Clean the electrode sites per skin preparation as discussed above.
- Attach the electrode to the snap end of the leadwires one at a time before applying the electrodes to the patient.
- 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.
AHA 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 second intercostal space.

**NOTE:** Place leg electrodes on thighs per note below.

<table>
<thead>
<tr>
<th>AHA</th>
<th>Lead Placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>RA</td>
<td>White <strong>Right Arm</strong></td>
</tr>
<tr>
<td>LA</td>
<td>Black <strong>Left Arm</strong></td>
</tr>
<tr>
<td>RL</td>
<td>Green <strong>Right Leg</strong></td>
</tr>
<tr>
<td>LL</td>
<td>Red <strong>Left Leg</strong></td>
</tr>
<tr>
<td>V1</td>
<td>Red</td>
</tr>
<tr>
<td>V2</td>
<td>Yellow</td>
</tr>
<tr>
<td>V3</td>
<td>Green</td>
</tr>
<tr>
<td>V4</td>
<td>Blue</td>
</tr>
<tr>
<td>V5</td>
<td>Orange</td>
</tr>
<tr>
<td>V6</td>
<td>Purple</td>
</tr>
</tbody>
</table>
IEC Lead Placement

**NOTE:** Place Leg electrodes on thighs per note below.

<table>
<thead>
<tr>
<th>IEC</th>
<th>Lead Placement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>Right Arm</td>
<td>Place the electrode on the inside of the right arm on the fleshy part of the arm between the shoulder and elbow</td>
</tr>
<tr>
<td>Yellow</td>
<td>Left Arm</td>
<td>Place the electrode on the inside of the left arm on the fleshy part of the arm between the shoulder and elbow</td>
</tr>
<tr>
<td>Black</td>
<td>Right Leg</td>
<td>Place the electrode slightly on the inside of the right thigh on the fleshy part of the leg between the hip and knee</td>
</tr>
<tr>
<td>Green</td>
<td>Left Leg</td>
<td>Place the electrode slightly on the inside of the left thigh on the fleshy part of the leg between the hip and knee</td>
</tr>
<tr>
<td>Red</td>
<td></td>
<td>Fourth intercostal space to the right of the sternum</td>
</tr>
<tr>
<td>Yellow</td>
<td></td>
<td>Fourth intercostal space to the left of the sternum</td>
</tr>
<tr>
<td>Green</td>
<td></td>
<td>Directly between leads V2 and V4</td>
</tr>
<tr>
<td>Brown</td>
<td></td>
<td>Fifth intercostal space at the midclavicular line</td>
</tr>
<tr>
<td>Black</td>
<td></td>
<td>Horizontal with V4 at left anterior axillary line</td>
</tr>
<tr>
<td>Violet</td>
<td></td>
<td>Horizontal with V5 at midaxillary line</td>
</tr>
</tbody>
</table>
Leadwire Color Identification

Each leadwire 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</td>
</tr>
<tr>
<td>V2</td>
<td>Yellow</td>
</tr>
<tr>
<td>V3</td>
<td>Green</td>
</tr>
<tr>
<td>V4</td>
<td>Blue</td>
</tr>
<tr>
<td>V5</td>
<td>Orange</td>
</tr>
<tr>
<td>V6</td>
<td>Purple</td>
</tr>
<tr>
<td>LA</td>
<td>Black</td>
</tr>
<tr>
<td>RA</td>
<td>White</td>
</tr>
<tr>
<td>LL</td>
<td>Red</td>
</tr>
<tr>
<td>RL</td>
<td>Green</td>
</tr>
</tbody>
</table>
Linking Voice Signature Data to Patient Demographics

Within the Mason Protocol software application, voice signature data is analyzed and compared to a data sample stored within a site-specific biometric voice database. The Mason Protocol software application uses a proprietary method of voice data analysis to match the voice data with the patient voice data stored in the application, and then displays the best “match”, allowing the clinicians to link voice/ECG data with existing demographic information within the software application.

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

Collecting a voice sample is one of several methods to associate ECG data to patient demographics and is popular in clinical research settings.

Voice Signature Data

1. Press the Main Function button on the Spaulding iQ ECG Acquisition Module one time to verify the letter “E” (EMPTY) appears on the LED Status Window on the Spaulding iQ ECG Acquisition Module.

   NOTE: If the letter “F” (FULL) is displayed on the LED Status Window on the Spaulding iQ ECG Acquisition Module, follow the instructions in Signal and ECG Data Transfer to Computing Device section to download data from the Spaulding iQ ECG Acquisition Module to the Computing Device.

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

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

3. Attach the ECG electrodes to the ECG leadwires as instructed in Patient Preparation section.

4. Mark the electrode locations on the patient, then apply the ECG electrodes to the patient as described in the Patient Preparation section.

   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.

5. 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.

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 LED Status 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 for the voice sample data analysis to occur.

**NOTE:** If the letter “r” displayed in the LED Status Window begins to blink, the data recording has exceeded 30 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 (for clinical research applications)**

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 has elapsed between voice and ECG 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

If a voice data recording is of poor quality, or is <10 seconds, the operator has the ability to delete it and re-record a new voice sample. 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 LED Status Window while the voice data is erased from the Spaulding iQ Acquisition Module.

2. Verify the letter “E” (EMPTY) re-appears on the LED Status Window.

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 ECG 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 three horizontal bars are displayed.

<table>
<thead>
<tr>
<th>One Horizontal Bar</th>
<th>ECG signal quality is poor. ECG Data that will be collected by the Acquisition Module may not provide sufficient data for analysis purposes. It is recommended that the patient be prepped and new electrodes be applied.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two Horizontal Bars</td>
<td>ECG signal quality is marginal. ECG Data that will be collected by the Acquisition Module may provide sufficient data for analysis purposes. Check the quality of the ECG data after download. It is recommended that the patient be prepped and new electrodes be applied.</td>
</tr>
<tr>
<td>Three Horizontal Bars</td>
<td>ECG signal quality is excellent. ECG Data that will be collected by the Acquisition Module is sufficient for data analysis purposes.</td>
</tr>
</tbody>
</table>

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 LED Status Window.

5. After 5 minutes of ECG data recording, the ECG data collection will automatically stop. The operator can depress the *Main Function* button prior to 5 minutes to manually terminate the recording prior to 5 minutes.

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

This section describes the steps required to transfer ECG data, and if applicable, voice data from the Spaulding iQ ECG Acquisition Module to the Computing Device using the Mason Protocol software application.

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

1. If necessary, log into the Computing Device.
2. Connect the larger end of the USB Cable to the USB Cable Port on the Computing Device. 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 a Spaulding Clinical, LLC Client Services Representative.

5. When the Spaulding iQ ECG Acquisition Module is automatically detected by the Computing Device 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 Computing Device. 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 sample in the system.

8. You can review the voice data by clicking the **Play Voice** button if audio verification is necessary.

---

**New Patient Enrollment**

**NOTE:** If a patient’s voice data sample was not previously uploaded to the client database, a voice match cannot occur 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 site by site basis.

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

NOTE: Patient demographic data can only be changed by Spaulding Clinical Client Services Representative or site designated super user (as specified in site configuration) once the Add Subject (patient) window is closed. Modification to this information is allowed through a designated site administrator or Spaulding Clinical Client Services Representative.

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 ECG data will automatically occur between the Computing Device 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 Computing Device 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 (patient) voice pairing within the Computing Device 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 list.

6. Click the Associate Visit button.
7. The transfer of ECG data will automatically occur between the Computing Device 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 Computing Device 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**
  - 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

---

*ECG Report*

*Spaulding Clinical ECG Report*

*Study / Subject Data*

- 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

---

*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 Computing Device 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 demographics from the site list.
- The voice data and ECG data is downloaded from the Spaulding iQ ECG Acquisition Module and remains on the Computing Device 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 data is stored to the Computing Device until internet connection is re-established.

1. Follow the steps in the **Voice Signal and ECG Data Transfer to Computing Device** 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 Computing Device 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 Computing Device to the CIMS will occur.
**Troubleshooting**

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

**LED Status Window 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>Low Battery “L”</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>No display</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 LED Status Window.</td>
</tr>
<tr>
<td>FULL “F”</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 Computing Device</em> section of the manual.</td>
</tr>
<tr>
<td>Frozen in UPLOAD MODE “U”</td>
<td>Spaulding iQ Acquisition module is locked in firmware upload mode.</td>
<td>Call Spaulding Client Services</td>
</tr>
</tbody>
</table>
| 1 BAR                       | ECG signal 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                       | ECG signal 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><strong>Biometric or Voice Signature data match cannot be established.</strong></td>
<td>Poor voice quality due to: &lt;ul&gt;&lt;li&gt;No voice collected&lt;/li&gt;&lt;li&gt;Acquisition module too far from patient during recording&lt;/li&gt;&lt;li&gt;Patient voice recording too quiet&lt;/li&gt;&lt;li&gt;Too much background noise during recording&lt;/li&gt;&lt;/ul&gt;</td>
<td>Follow the steps in Recording Voice Signature and ECG Data section of the manual.</td>
</tr>
<tr>
<td><strong>Voice Signature Data is erased</strong></td>
<td>If the inactivity time after recording voice exceeds 4 minutes, this 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><strong>Poor Quality ECG displayed in the pdf rendering</strong></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 Computing Device

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Probable Cause</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Error message: “ECG transmission failed, Please check internet connection” To postpone the upload attempt, click the button below.</strong></td>
<td>Loss of internet connection</td>
<td>&lt;ul&gt;&lt;li&gt;Follow the steps in “Off-line Workflow” section of the manual.&lt;/li&gt;&lt;li&gt;Check the internet connection. Call your internal IT Support Group and Spaulding Client Services.&lt;/li&gt;&lt;/ul&gt;</td>
</tr>
<tr>
<td><strong>Error Message: “ECG cannot be processed – Spaulding Clinical is investigating”</strong></td>
<td>Insufficient ECG data, collected less than 1 minute recommended ECG data sample.</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 or your site administrator.</td>
</tr>
</tbody>
</table>
Index

A
Acquisition Module  1, 2, 3, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 19, 21, 22, 23, 24, 25, 29, 30, 31, 32, 33, 34, 40, 43
Associate Visit  36, 38

B
Battery
LOW BATTERY  22, 23, 29

C
Cable Port
  ECG Cable Port  16, 24, 29
  USB Cable Port  16, 23, 33
CAUTIONS  8
CIMS  1, 19, 33, 36, 39, 41
Cleaning Instructions  14
Client Services Representative  19, 20, 34
Computing Device  1, 8, 9, 11, 15, 19, 20, 22, 23, 29, 32, 33, 34, 36, 38, 39, 40, 41, 43, 44
Copyright and Trademark Notices  3

D
Device Data Summary  34
Display Code  22, 43

E
ECG
  ECG Acquisition Module  1, 2, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 25
  ECG Cable Port  16
  ECG data  1, 2, 9, 17, 22, 25
  ECG transmission  40, 44
  View ECG  37
Electrode  1, 25, 26, 43
Electrode Location  25, 43
Electrode Location Preparation  25, 43
Electrode Placement  25, 26, 43
Electromagnetic Compatibility  10
Equipment Preparation  19, 21, 43
Erase Indicator  22, 31

F
Follow Up Visit  38
Frequency of Use  2

G
General Care  14
Guidance and Manufacturer’s Declaration  10, 11

I
Indications for Use  2
Intended Users  2
Internet Connection  40, 41, 44

L
Lead Quality Check  17
Leadwire Color Identification  28
LED Status Window  17, 21, 23, 29, 30, 31, 32, 43

M
Main Function  14, 16, 29, 30, 31, 32
Maintenance and troubleshooting  1
Maintenance & Troubleshooting  43
Manufacturer’s Responsibility  3
Mason Protocol  1, 9, 18
Mason Protocol Software
  Mason Protocol Software Installation  19
Microphone  5, 16

N
New Patient Enrollment  35, 40

O
Off-line Mode  37, 40
Off-line Workflow  40, 44
On-line Mode  37
Other Important Information  3

P
Patient Cable  1, 2, 6, 10, 14, 15, 17, 21, 24, 29
10-leadwire Patient Cable  1, 2, 6, 10, 15
Patient Demographics  1, 38, 40
Patient Population  2
Patient Preparation  24, 25, 29, 43
Preparing Patient Skin for ECG Hookup  26, 43

R
Responsibility of the End User  3
Return Patient  38

S
Serial Number Identification  3
Spaulding iQ
  Spaulding iQ ECG Acquisition Module  1, 2, 6, 7, 8, 10, 11, 12, 13, 14, 15, 16, 17, 21, 23, 24, 25, 29, 30, 31, 32, 33, 34, 40
Spaulding iQ Electrocardiograph system  6
Spaulding iQ Electrocardiograph System  1, 2, 3, 6, 15
Specifications  17, 18, 19
System Information  1

U
User Safety Information  6

V
Visit Confirmation  36, 38
Visit Designation  36, 39
Voice Pairing Confirmation  38
Voice Recording
  Voice data  1, 2, 22, 29, 30, 31, 34, 35
  Voice Recording Example Script  30
  Voice Signal  23, 32, 33, 40, 43

W
WARNINGS  6