Baxter

Welch Allyn
RScribe Lite
12-Lead Electrocardiograph System

Instructions for use

Baxter Technical Support
For information about any Baxter product, contact Baxter Technical Support:
www.baxter.com/contact-us

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901151 RSCRIBE LITE ELECTROCARDIOGRAPH

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Hillrom™

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Notices

Manufacturer's Responsibility

Welch Allyn, Inc. is responsible for the effects on safety and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out only by persons authorized by Welch Allyn, Inc.
- The device is used in accordance with the instructions for use.

Responsibility of the Customer

The user of this device is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Equipment Identification

Welch Allyn, Inc. equipment is identified by a serial and reference number on the back of the device. Care should be taken so that these numbers are not defaced. Software equipment is accompanied by an identification card; carefully store this card as the information is needed for activation, upgrade and customer service.

Copyright and Trademark Notices

Other Important Information

The information in this document is subject to change without notice.

Welch Allyn, Inc. makes no warranty of any kind with regard to this material including, but not limited to, implied warranties of merchantability and fitness for a particular purpose. Welch Allyn, Inc. assumes no responsibility for any errors or omissions that may appear in this document. Welch Allyn, Inc. makes no commitment to update or to keep current the information contained in this document.

Notice to EU Users and/or Patients

Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Warranty Information

Your Welch Allyn Warranty

WELCH ALLYN, INC. (hereafter referred to as "Welch Allyn") warrants that components within Welch Allyn products (hereafter referred to as "Product/s") will be free from defects in workmanship and materials for the number of years specified on documentation accompanying the product, or previously agreed to by the purchaser and Welch Allyn, or if not otherwise noted, for a period of twenty-four (24) months from the date of shipment.

Consumable, disposable or single use products such as, but not limited to, PAPER or ELECTRODES are warranted to be free from defects in workmanship and materials for a period of 90 days from the date of shipment or the date of first use, whichever is sooner.

Reusable product such as, but not limited to, BATTERIES, BLOOD PRESSURE CUFFS, BLOOD PRESSURE HOSES, TRANSDUCER CABLES, Y-CABLES, PATIENT CABLES, LEAD WIRES, MAGNETIC STORAGE MEDIUMS, CARRY CASES or MOUNTS, are warranted to be free from defects in workmanship and materials for a period of 90 days. 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 Welch Allyn;

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 Welch Allyn;

f) Other events outside of Welch Allyn'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, OR ANY PRODUCT/S FOUND UPON EXAMINATION BY WELCH ALLYN TO HAVE BEEN DEFECTIVE. This remedy shall be conditioned upon receipt of notice by Welch Allyn of any alleged defects promptly after discovery thereof within the warranty period. Welch Allyn'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 Welch Allyn's principal place or any other place as specifically designated by Welch Allyn or an authorized distributor or representative of Welch Allyn, and (ii) all risk of loss in transit. It is expressly agreed that the liability of Welch Allyn is limited and that Welch Allyn does not function as an insurer. A purchaser of a Product/s, by its acceptance and purchase thereof, acknowledges and agrees that Welch Allyn is not liable for loss, harm, or damage due directly or indirectly to an occurrence or consequence there from relating to the Product/s. If Welch Allyn should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Welch Allyn shall be limited to the lesser of the actual loss, harm, or damage, or the original purchase price of the Product/s when sold.

EXCEPT AS SET FORTH HEREIN WITH RESPECT TO REIMBURSEMENT OF LABOR CHARGES, A PURCHASER'S SOLE EXCLUSIVE REMEDY AGAINST WELCH ALLYN 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 WELCH ALLYN IS NOTIFIED WITHIN THE WARRANTY PERIOD. IN NO EVENT, INCLUDING THE CLAIM FOR NEGLIGENCE, SHALL WELCH ALLYN 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.

User Safety Information

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.

NOTE: This manual may contain screen shots and pictures. Any screen shots and pictures are provided for reference only. Consult the actual screen in the host language for specific wording.

WARNINGS

1. This manual gives important information about the use and safety of this device. Deviating from operating procedures, misuse or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the device.
2. Device 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.
3. Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device. Contact Baxter service for additional training options.
4. 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 Baxter.
5. 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.
6. Conductive parts of the patient cable, electrodes, and associated connections of type CF applied parts, including the neutral conductor of the patient cable and electrodes, should not come into contact with other conductive parts including earth ground.
7. Do not attempt to clean the patient cables by submersing into a liquid, autoclaving, 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. Use of unspecified cleaning/disinfecting agents, failure to follow recommended procedures, or contact with unspecified materials could result in increased risk of harm to users, patients and bystanders, or damage to the device.
8. The device is part of an integral personal computer-based diagnostic system. The user must adhere to all warnings in order to ensure safe and reliable performance.
9. If operated on AC (~) power, the personal computer must be connected with its original power cable to an electrical installation that complies with applicable regulations for environments where patients are treated.
10. The personal computer used and any peripheral devices connected to it must be approved to the appropriate safety standard for nonmedical information technology equipment per IEC 60950, or its national variants. The personal computer and any peripheral devices connected to it, being non-medical

electrical equipment, must be situated outside the patient environment per IEC 60601-1–1. To ensure the safety of the patient it must not be possible for the operator to touch the patient and the computer at the same time. In general, at least 1.5 meters (5') of open area must surround the patient to achieve this.

11. If the personal computer is situated within the patient environment, ensure that its level of safety is that of medical electrical equipment per IEC 60601-1. This may be accomplished by powering the computer and any other equipment connected to it through an isolation transformer or by operating on battery power.
12. If the personal computer is situated within the patient environment, to maintain designed operator and patient safety when a LAN network connection is being used, the network cable must be connected to the device through an Ethernet isolator module that complies with IEC 60601-1-1 (available from Baxter).
13. ECG electrodes could cause skin irritation; patients should be examined for signs of irritation or inflammation. Electrode materials and ingredients are specified on the packaging or are available from the vendor upon request.
14. To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with device or patient cables. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.
15. Proper clinical procedure must be employed 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. Do not mix electrodes made of dissimilar metals.
16. 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.
17. A possible explosion hazard exists. Do not use the device in the presence of flammable anesthetic mixture.
18. Possible malfunction risks may be present when installing third-party software. Baxter cannot verify the compatibility of all possible hardware/software combinations.
19. 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.
20. When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise cannot be reduced by proper procedures.
21. The quality of the signal produced by the device may be adversely affected by the use of other medical equipment, including but not limited to defibrillation and ultrasound machines.
22. Use only recommended alkaline battery cells with **WAM**. Use of other cells may present a risk of fire or explosion.
23. The **WAM** low battery warning function is designed for alkaline battery cells only. Use of other cells may result in failure of the low battery warning possibly resulting in a malfunction of the device.
24. When the **RScribe** Lite application is optionally installed on the cardiac stress exercise system, refer to the stress system user manual for additional warnings.
25. Test **RScribe** Lite functions after each **Microsoft** critical and security update with a simulator prior to patient use.
26. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.
27. To prevent emission of substances that may damage the environment, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials that are past the shelf life in accordance with local regulations.

28. When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
29. Proper functioning backup items such as a spare patient cable, display monitor, and other equipment are recommended on hand to prevent delayed treatment due to an inoperable device.

FCC Compliance Statement for the **WAM**

In the United States use of this device is regulated by the Federal Communications Commission (FCC). The **WAM** with its antenna complies with FCC's RF exposure limits for general population/uncontrolled exposure.

FCC Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.

WAM FCC ID: HJR-WAM2500
UTK FCC ID: HJR-UTK2500

These devices comply with Part 15 of the FCC rules. Operation is subject to the following conditions:

1. This device may not cause harmful interference, and

2. This device must accept any interference received, including interference that may cause undesired operation.

Industry Canada Compliance Statement

These devices comply with RSS-210 of the Industry Canada rules. Operation is subject to the following two conditions:

1. This device may not cause interference, and

2. This device must accept any interference, including interference that may cause undesired operation of the device.

WAM IC: 3758B-WAM2500
UTK IC: 3758B-UTK2500

The term **"IC:"** before the certification/registration number only signifies that the Industry Canada technical specifications were met.

CAUTIONS

1. Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Patient cables should be stored after forming them into a loose loop.
2. Proper functioning backup items such as a spare patient cable, front-end device, display monitor, and other equipment are recommended on hand to prevent delayed treatment due to an inoperable device.
3. **Windows** updates and anti-virus policy: Although it is unlikely that **Windows** updates and security patches affect **RScribe** Lite functionality, Baxter recommends turning automatic **Windows** update off, and periodically running it manually. A functional test should be executed after update, which includes acquiring a recording, editing and printing a report, as well as importing an order and exporting results, if activated. Baxter recommends excluding the **RScribe** Lite database folder (normally C:\ProgramData\MiPgSqlData on a stand-alone system or the server) and main application folder (normally C:\Program Files (x86)\Mortara Instrument Inc\ModalityMgr) from the folders to be scanned. In addition, anti-virus patch updates and system scans should be scheduled for time periods when the system is not actively in use or performed manually.
4. No other non-recommended PC application software should be running while the **RScribe** Lite application is being used.
5. It is recommended that all resting ECG workstations and review stations be periodically updated with **Microsoft** critical and security updates to protect from malware attacks and to fix critical **Microsoft** software issues.
6. To prevent delivery of malware into the system Baxter recommends that institution operating procedures are written to prevent malware to be transmitted into the system from removable media.
7. The **WAM** will only work with receiving devices that are equipped with the appropriate option.
8. This **WAM** is not recommended for use in the presence of imaging equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) devices, etc.
9. The following equipment may cause interference with the **WAM** RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.
10. AA batteries are known to leak their contents when stored in unused equipment. Remove battery from **WAM** when not used for an extended period of time.
11. Be careful to insert the correct lead wire into the connector block with the appropriate input connector by matching the lead wire labels to the **WAM** or **AM**12 lead labels.
12. Federal law restricts this device to sale by or on the order of a physician.

Notes

1. Local Administrator permissions are required for software installation, application configuration, and software activation. Local User privileges are required for application users. Roaming and temporary accounts are not supported.
2. 8-hour timeout expiration is automatically controlled by the system. Each operation that occurs (e.g. Exam Search, Patient Search, editing exams, starting an exam, etc.) will reset the timeout start time. When there is no interaction with the system for the timeout duration, the user is prompted to enter login information.
3. When the server is unavailable in a distributed configuration, the client workstation will notify the user with a prompt to proceed in Offline Mode or cancel. Scheduled orders are not available. An exam can be conducted with manually entered demographics and will be stored locally. When the server comes available, the user is prompted with a list of unsent exams and a selection to send exams to the modality manager database.
4. Patient movements may generate excessive noise that may affect the quality of the ECG traces and the proper analysis performed by the device.
5. Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
6. 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.
7. If an electrode is not properly connected to the patient, or one or more of the patient cable lead wires is damaged, the display will indicate a lead fault for the lead(s) where the condition is present.
8. A thick baseline presentation on the display while using the **AM**12 may be due to a calibration error. Review the LED indicator on the **AM**12 to ensure the unit is connected, or disconnect and reconnect to the PC USB port to re-calibrate.
9. The **WAM** will automatically start flashing LEDs if the batteries have been discharged below 1.0 volts.
10. During normal **WAM**/**AM**12 operation, the green LED will display continuously.
11. If the **WAM** battery cover is opened during transmission, the device will stop transmitting. The battery must be reinserted and the cover must be applied to resume operation.
12. The **WAM** will automatically turn off (LEDs off) if the battery has been severely discharged.
13. The **WAM** will automatically turn off when the electrocardiograph is powered down.
14. The **WAM** will automatically turn off after being disconnected from the patient. This will happen regardless of **RScribe** Lite battery/AC power state.
15. A thick baseline presentation on the display while using the **WAM** may be due to the **WAM** being turned off, having no battery, not being paired correctly, operating out of range, or due to a calibration error. Review the LED indicator and auditory advisory on the **WAM** to ensure the unit is turned on, has proper battery level, is paired correctly, and is within recommended proximity of the electrocardiograph, or power cycle the **WAM** to re-calibrate.
16. As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:

    - Type CF, defibrillation-proof applied parts.

17. If not specifically indicated otherwise, personal computer equipment used with the device can be regarded as:
    - Class I (if the computer has a three-prong power inlet) or class II (if it has a two-prong inlet)
    - Ordinary equipment.
    - Equipment not suitable for use in the presence of a flammable anesthetic mixture.
    - Continuous operation.

18. To prevent possible damage to the device during transport and storage (while in original packaging) the following environmental conditions must be adhered to:

Ambient temperature:	-20° C to 65° C (-4° F to 149° F)
Relative humidity:	10% to 95%, non-condensing

19. Allow the device and any computer equipment used to stabilize within its intended operating environment for a minimum of two hours prior to use. Refer to the computer equipment user manual for allowable environmental conditions. The allowable environmental conditions for the **AM**12 and **WAM** acquisition modules are as follows:

Ambient temperature:	10° C to 40° C (50° F to 104° F)
Relative humidity:	10% to 95%, non-condensing

20. The **WAM** is UL classified:

    WITH RESPECT TO ELECTRIC SHOCK,
    FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
    UL2601-1, IEC60601-1, CAN/CSA CC22.2 No. 601.1, IEC60601-2-25,

Equipment Symbols and Markings

Symbol Delineation

WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. In addition, when used on a patient applied part, this symbol indicates defibrillation protection is in the cables. Warning symbols will appear with a grey background in a black and white document.

CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.

Defibrillator-proof type CF applied part

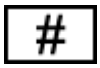
Refer to instruction manual / booklet.

USB connection to PC

Indicates a separate waste collection is required for Waste of Electrical and Electronic Equipment (WEEE).

Medical Device

Reorder Number



Model Identifier

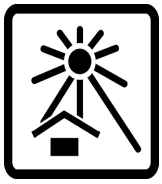
NOTE: Refer to the manual(s) accompanying the device that pertain to the computer hardware for additional definitions of symbols that may be present.

Package Symbol Delineation

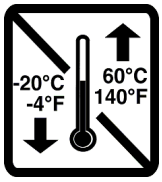
This side up

Fragile

Keep Dry



Keep Away from Heat



Acceptable Temperature Range

Introduction

Manual Purpose

This manual is intended to provide the user with information about the **RScribe** Lite resting electrocardiograph's display screen, menu structure, icons, and navigation tools.

NOTE: This manual contains screen images that are for illustration and might be different in the actual product. Consult the actual screen in the host language for specific wording.

Audience

This manual is written for clinical professionals with a working knowledge of medical procedures and terminology as required for monitoring cardiac patients.

Intended Use

The **RScribe** Lite Electrocardiograph is a multi-channel electrocardiograph product used for acquiring, analyzing, displaying and printing resting ECG's. The **RScribe** Lite is a 12-channel diagnostic electrocardiograph intended for recording and printing ECG's of adult and pediatric patients. The acquired ECG will be displayed for quality check purpose, analyzed using the Baxter **VERITAS** resting interpretation, optionally printed, stored and/or transmitted to a ECG Management System or Hospital Information System. The device is not intended to be used as a vital signs physiological monitor.

It is a system comprised of a Baxter ECG amplifier (Wireless Acquisition Module [**WAM**] or **AM**12 Patient Cable) and an off-the-shelf personal computer with Baxter software application that allows clinicians to collect ECGs on patients during routine visits. The patient populations for which the device will be used may be healthy or diseased of any age. ECG's are taken with the patient in the supine position. The **RScribe** Lite is intended to be used by a licensed health care practitioner in a hospital, medical clinic and offices of any size, including Clinical Research Organizations.

Indications for Use

The **RScribe** Lite electrocardiograph is a non-invasive prescription device.

- The device is indicated for use to acquire, analyze, display, transmit and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG offered 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.
- The device is indicated for use on adult and pediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.
- The device is not designed for out of hospital transport.
- The device is not designed for use in highly invasive environments, such as an operating theatre.

System Description

RScribe Lite is a multi-lead, diagnostic, computer-based resting electrocardiograph capable of acquiring, viewing, transmitting, printing, and storing ECG data.

RScribe Lite models ordered with the **VERITAS** resting ECG interpretation algorithm option are capable of specific age and gender interpretation criteria. The **VERITAS** algorithm provides an over-reading physician with a silent second opinion through diagnostic statements displayed on the ECG report. For additional information on the **VERITAS** algorithm, please refer to the Physician's Guide to **VERITAS** with Adult and Pediatric Resting ECG Interpretation (see Accessories).

RScribe Lite can be configured with bidirectional connectivity and **DICOM** protocol support.

RScribe Lite is integrated with a multi-modality patient and exam management system called Modality Manager. Modality Manager handles the scheduling of exams, database storage and maintenance, exam and patient search, printing, communication with external systems and dispatches the modality dependent acquisition and review functions. **RScribe** Lite can be configured for data distribution. When so configured, the database resides on a server supporting a number of networked client workstations.

The **RScribe** Lite Review software offers authorized users with the ability to schedule new exams when not linked to an external scheduling system, view reports, enter conclusions, and generate printed or electronic reports for completed exams.

The **RScribe** Lite supports print formats that include:

- Standard or Cabrera
- 3+1
- 3+3
- 12
- 6+6 channel in automatic mode
- Single channel on one page (60 min of acquired ECG for rhythm strip (Full Disclosure) printing

The **RScribe** Lite packing list includes:

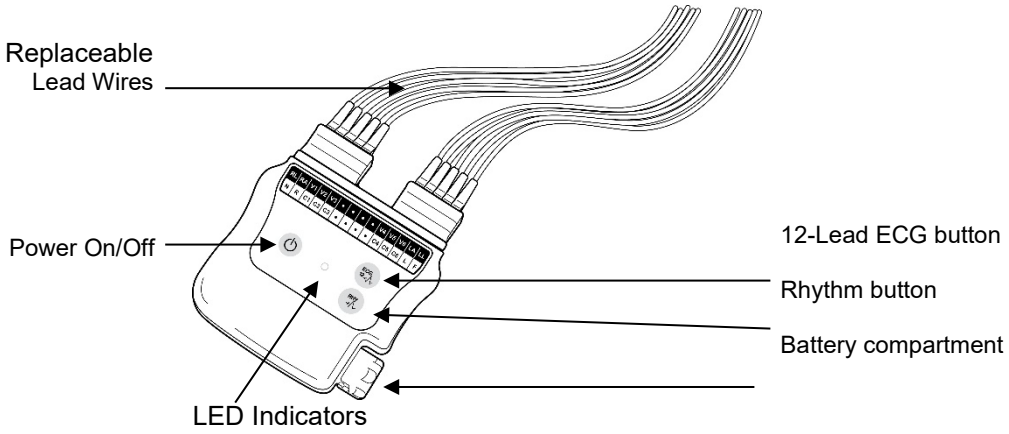
- Acquisition module with lead wire set
- Accessory starter kit

Acquisition Module Types

Two acquisition module types, the Wireless Acquisition Module (**WAM**) or **AM**12 patient cable, for ECG acquisition are used with **RScribe** Lite.

WAM with Lead Wires

Figure 1 WAM with Lead Wires



The **WAM** incorporates frequency-hopping technology in the 2500 MHz frequency range with 40,000 Hz ECG acquisition and is operated by two buttons located on the front of the device when used with **RScribe** Lite:

1. Power On/Off
2. Acquiring a 12-lead ECG

NOTE: Rhythm button is non-functional.

The **WAM** uses one AA alkaline, 1.5V battery for approximately 8-hours of continuous operation.

WARNING: Use of other cells may present a risk of fire or explosion.

USB Transceiver Key (**UTK**)

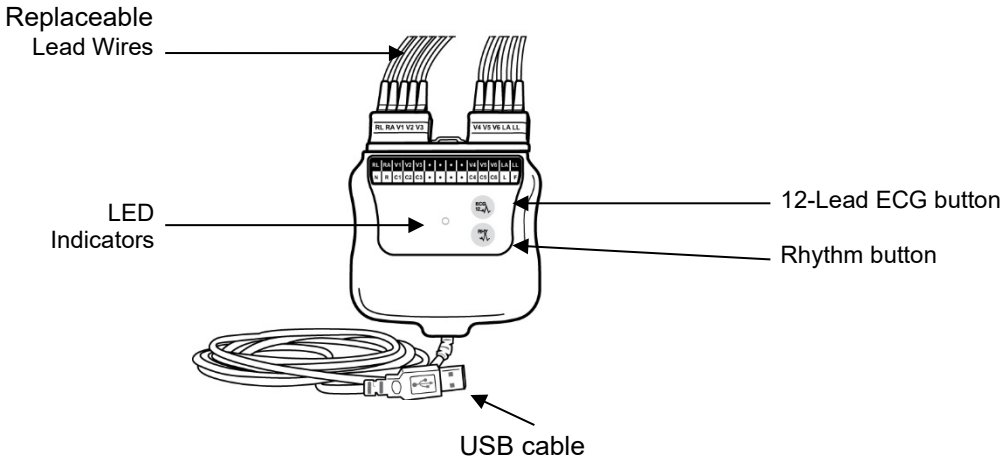
The **UTK** connected to the **RScribe** Lite USB port receives ECG signals from the paired **WAM** for presentation of the electrocardiogram. The **UTK** connected to USB cable (6400-015) from the PC port is positioned in an unobstructed location.

WAM LED Indicators

LED	+ Audio	MODE
GREEN off YELLOW off	Intermittent beeping	**WAM** is on but not paired to an electrocardiograph, is out of range of the paired electrocardiograph.
YELLOW solid or flashing GREEN off		One or more leads are not connected properly.
GREEN solid YELLOW off		No lead fail condition is detected; battery is OK.
GREEN solid YELLOW off	Intermittent beeping	**WAM** is collecting a 10-second ECG.
Blinking LED (yellow or green depending on lead fault status)		**WAM** has detected a low battery condition. Replace the battery within 15 minutes.
GREEN off YELLOW off	1 second audio on, then device turns off.	**WAM** has detected a very low battery status and powered off.

AM12 with Lead Wires

Figure 2 AM12 with Lead Wires



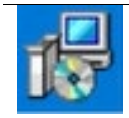
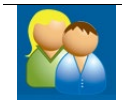
The **AM**12 is available for a traditional wired connection with direct USB connection and 40,000 Hz ECG acquisition. The 12-Lead ECG button can be used to acquire a 12-lead ECG at the patient's side.

NOTE: Rhythm button is non-functional.

Lead Fail

Lead fail is done automatically through visual communication with the LEDs located on the front of the **WAM** and **AM**12. A yellow LED (solid or flashing) indicates a lead fail condition is present. A solid green LED indicates proper lead connection as well as adequate **WAM** battery voltage for ECG acquisition.

RScribe Lite Program Icons and Descriptions

Icon and Hover Text	Description
	Desktop shortcut icon to launch the Resting ECG application.
 Schedule/Orders	Opens a window with two selectable tabs. A MWL (Modality Work List) tab allows exam scheduling (when no orders interface exists) and schedule review. A Patients tab allows addition of new patient information and editing of existing patient information.
 STAT ECG Test	Use to bypass Exam Data Entry and proceed directly to real-time ECG for immediate acquisition
 Start a Resting Exam	Use to enter exam data and begin real-time ECG acquisition
 Exam Search	Use to search for exams in the database using filters.
 User Preferences	Use to configure user preferences for the Worklist and to change the password.
 System Configuration	For administrative users to configure system settings such as creating/modifying users, changing the **RScribe** Lite default acquisition criteria, defining archive directories, and so on.
 Exit	Use to close the **RScribe** Lite application and return to the desktop.
	Use to minimize or exit the application and return to the desktop.

User Roles and Permissions

RScribe Lite supports a workflow-oriented setup for defining user roles and controlling user access to the various operations. Role assignments are comprised of a set of permissions for each user type (e.g. IT administrator, clinical administrator, ECG Tech, and so on).

Each user can be assigned a single role or a combination of roles. Some roles will include permissions assigned to other roles where applicable. After installation, a single user is created, with the role of "IT Administrator". Before using **RScribe** Lite, this user should log in and create required users and roles.

Roles	Permission Assignment
IT Administrator	Manage user permissions; manage personnel lists; export settings; archive settings; workflow configuration; storage system configuration; unlock exams; view audit trail reports; export service logs; create and modify groups.
Clinical Administrator	Manage database exams (delete, archive, and restore); copy exams offline to share with Baxter personnel or other sites; view audit trail reports; modify modality settings (profiles, protocols, and other resting ECG specific settings); reconcile; export service logs.
Schedule Procedure	Create new patient orders; associate an order with an existing patient; modify demographics of an existing patient; export service logs. Scheduling and order entry is only available when **RScribe** Lite is not linked to an external scheduling system.
Patient Hookup (Start a Resting Exam)	Ability to start a test using Start a Resting Exam icon. Includes the ability to create a new patient; associate an order with an existing patient; export service logs.
Edit Holter Diary	Not applicable to the **RScribe** Lite application.
View Exams/Reports	Review exams and final reports only. Includes the ability to search exams, view and print reports; export service logs.
Prepare Report	Review and edit exams to move them from an acquired state to the edited state. Includes ability to search exams and view and print reports; export service logs.
Review and Edit Report	Review and edit exams to move them to the reviewed state. Includes ability to search exams and view and print reports; modify and create conclusions; export service logs.
Edit Conclusions	Create and modify conclusions. Includes ability to review exams and final reports only; search exams and view and print reports; export service logs.
Sign Report	Ability to move exams to a signed state. Includes ability to review exams and final reports; search exams and view and print reports; export service logs. May require user authentication.
Export Report	Ability to export a PDF and XML file when features are enabled. Must be assigned in conjunction with another role (e.g. Review, View, or Conclusions).