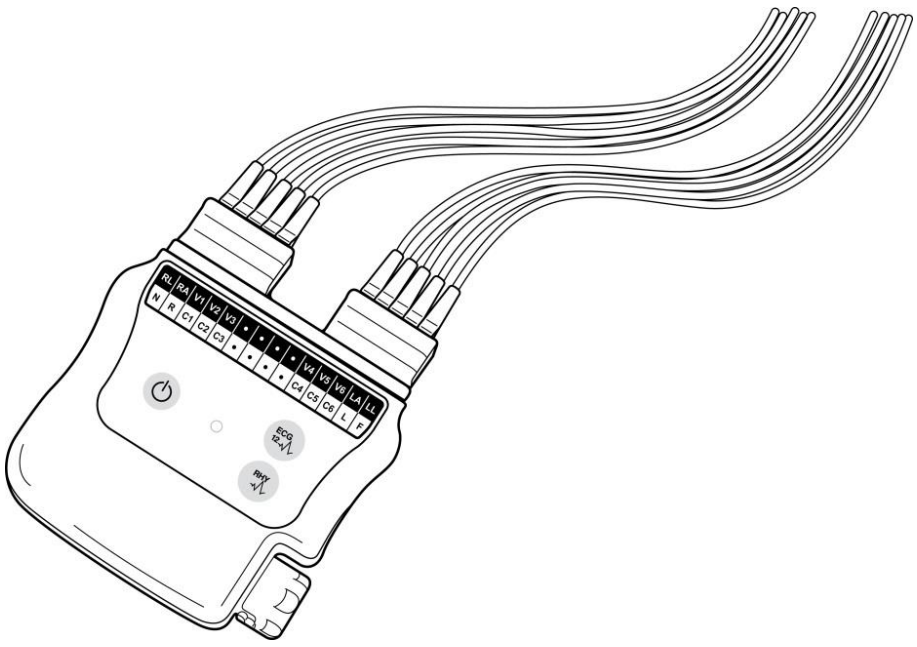
Hillrom™

Welch Allyn®

Diagnostic Cardiology Suite Wireless Acquisition Module™ and UTK™

User Manual



CAUTION Federal law restricts this device to sale by or on the order of a physician.

For information about any Welch Allyn product, visit: https://www.welchallyn.com/en/about-us/locations.html

For patent information, please visit www.welchallyn.com/patents

Customer Service and Technical Support: https://www.welchallyn.com/en/other/contact-us.html
1.888.667.8272, mor_tech.support@hillrom.com

This manual applies to the # 901128 CARDIOPULMONARY ECG SYSTEM and # 901095 ECG ACQUISITION MODULE

REF 9515-174-60-ENG Rev B
Revision date: 2019-07

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EC REP EU IMPORTER

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CE

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NOTICES

Manufacturer's Responsibility

Welch Allyn 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.
- 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 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.

Copyright and Trademark Notices

Other Important Information

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

Welch Allyn 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 assumes no responsibility for any errors or omissions that may appear in this document. Welch Allyn makes no commitment to update or to keep current the information contained in this document.

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 twelve (12) 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 therefrom 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.

WARNING(S)

- 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.

- Device transmits data reflecting a patient's physiological condition to a properly equipped receiving device 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.

- 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 service for additional training options.

- 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 Welch Allyn.

- Patient cables intended for use with the device include series resistance (9 Kohm minimum) in each lead for defibrillation protection. Patient cables should be checked for cracks or breakage prior to use.

- Conductive parts of the patient cable, electrodes, and associated connections of type CF applied parts, including the neutral conductor of the patient cable and electrodes, 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 irritation or inflammation.

- 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.

- Defibrillation protection is guaranteed only if the original patient cable is used. Any modification of this device may alter defibrillator protection.

- 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.

- This device was designed to use the electrodes specified in this manual. 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.

- 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.

- A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture.

- 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.

- 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 defibrillators and ultrasound machines.

- 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.

- Operations may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment.

- The battery-operated device transmits data reflecting a patient's physiological condition to a receiving device. During operation failure, data transmission and LCD information will cease to occur. In mission critical conditions, it is advisable to have a backup device available.

- Use only recommended alkaline battery cells. Use of other cells may present a risk of fire or explosion.

- 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.

- Do not attempt to clean the device or patient cables by submersing into a liquid, autoclaving, or steam cleaning as this may damage equipment or reduce its usable life. 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. Do not sterilize the device or patient cables with Ethylene Oxide (EtO) gas. Refer to *Maintenance* for proper cleaning and disinfection instructions.

Caution(s)

- To prevent possible damage to the device, do not use sharp or hard objects to depress buttons, only use fingertips.
- The device and lead wires should be cleaned between each use. Inspect connections for damage or excessive wear prior to each use. Replace lead wires if damage or excessive wear is noted.
- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Lead wires should be stored after forming them into a loose loop.
- The device will only work with receiving devices that are equipped with the appropriate option.
- No user-serviceable parts are inside. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.
- This device is not recommended for use in the presence of imaging equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) devices, etc.
- The following equipment may cause interference with the RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.
- When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
- AA batteries are known to leak their contents when stored in unused equipment. Remove battery from device when not used for an extended period of time.
- Be careful to insert the connector block into the appropriate input connector by matching the lead wire labels to the device label.
- To prevent possible damage to the device during transport and storage (while in original packaging) the following environmental conditions must be adhered to (for ECG accessories, such as electrodes, refer to applicable packaging):

  Ambient Temperature Range: -20°C to 65°C (-4°F to 149°F)
  Relative Humidity Range: 5% to 95% (non-condensing)
  Atmosphere Pressure: 500 hPa to 1060 hPa

- This device is intended to be used in a hospital or doctor's office setting, and should be used according to the environmental conditions specified below:

  Ambient Temperature Range: 0°C to 40°C (32°F to 104°F)
  Relative Humidity Range: 5% to 95% (non-condensing)
  Atmosphere Pressure: 500 hPa to 1060 hPa

Notes

- Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
- If electrode is not properly connected to the patient, or one or more of the patient cable lead wires is damaged, display will indicate a lead fault for the lead(s) where the condition is present.
- For additional instructions and warnings, refer to the user manual of the receiving device.
- As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:
  - Class I equipment or internally powered.
  - Type CF (ECG) defibrillation-proof applied parts.
  - Equipment not suitable for use in the presence of a flammable anesthetic mixture.
  - Continuous operation.
- The device will automatically start flashing LEDs if the battery has been discharged below 1.0 volts.
- During normal operation, the green LED will display continuously.
- If the 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.
- The device will automatically turn off (LEDs off) after two minutes of inactivity or user input. The device will turn off immediately if the device battery has been severely discharged.
- When pairing with the device, ensure the AM12 has been disconnected or the pairing operation will fail.
- A square wave presentation on the display while using the Welch Allyn Wireless Acquisition Module may be due to the device 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 device to ensure the unit is turned on, has proper battery level, is paired correctly, and is within recommended proximity of the UTK, or power cycle the Welch Allyn Wireless Acquisition Module to re-calibrate. See section on equipment preparation below for details.
- The Wireless Acquisition Module is UL classified:

WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH: ANSI/AAMI ES60601-1, CAN/CSA-C22.2 No. 60601-1, IEC 60601-1, IEC 60601-2-25

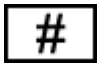
EQUIPMENT SYMBOLS AND MARKINGS

Documentation Symbols

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.

Miscellaneous symbols

	Defibrillator-proof type CF applied part
	Acquire 12 Lead ECG
	Acquire Rhythm Print
	On / Off button
	Battery with notification: See operating instructions for type of cell to be used.
	Do not dispose as unsorted municipal waste. Requires separate handling for waste disposal according to local requirements.
	Medical Device
	Meets essential requirements of the European Medical Device Directive 93/42/EC
	Reorder Number
	Model Identifier
	Follow instructions/directions for use (DFU) -- mandatory action. A copy of the DFU is available on this website. A printed copy of the

	DFU can be ordered from Welch Allyn for delivery within 7 calendar days.
	Non-Ionizing Electromagnetic Radiation
	Australian Communications and Media Authority (ACMA) Radio Compliance Mark (RCM).

GENERAL CARE

Precautions

- Turn off the device before inspecting or cleaning.
- Do not immerse the device in water.
- Do not use organic solvents, ammonia-based solutions, or abrasive cleaning agents which may damage equipment surfaces.

Inspection

Inspect your equipment daily prior to operation. If you notice anything that requires repair, contact an authorized service person to make the repairs.

- Verify that all cables and connectors are securely seated.
- Check the case for any visible damage.
- Inspect cables and connectors for any visible damage.
- Inspect buttons and controls for proper function and appearance.

Cleaning and Disinfection

Refer *Maintenance* for proper cleaning and disinfection procedures.

Sterilization

Do not sterilize the device or patient cables with Ethylene Oxide (EtO) gas.

Cautions

Improper cleaning products and processes can damage the device, produce brittle lead wires and cables, corrode the metal, and void the warranty. Use care and proper procedure whenever cleaning or maintaining the device.

ELECTROMAGNETIC COMPATIBILITY (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the device.

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

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

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See Table X-4 for recommended separation distances between the radio equipment and the device.

The use of accessories, transducers, and cables other than those specified by Welch Allyn may result in increased emissions or decreased immunity of the equipment.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF Emissions CISPR 11	Group 2	The equipment must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	The equipment 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.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment 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.

Immunity Test	Compliance	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Not Applicable	
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	Not Applicable	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	Not Applicable	
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: *UT is the AC Mains voltage prior to application of the test level.*

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment 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>
<tr><th>Emissions Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment: Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to
80 MHz</td><td>3 Vrms
150 kHz to
80 MHz</td><td rowspan="2">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

$d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$

$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz

$d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ 800 MHz to 2.5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].

Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to
2.5 GHz</td><td>3 V/m
80 MHz to
2.5 GHz</td></tr>
</table>

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

b. 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 Equipment

The equipment 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.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter (m)	
	150 KHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.1 m	0.2 m
0.1	0.4 m	0.7 m
1	1.2 m	2.3 m
10	4.0 m	7.0 m
100	12.0 m	23.0 m

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

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.*

Regulatory Radio Compliance

Federal Communications Commission (FCC)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the distance between the equipment and the receiver
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

The user may find the following booklet prepared by the Federal Communications Commission helpful: The Interference Handbook This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402. Stock No. 004-000-0034504. Welch Allyn is not responsible for any radio or television interference caused by unauthorized modification of the devices included with this Welch Allyn product, or the substitution or attachment of connecting cables and equipment other than specified by Welch Allyn. The correction of interference caused by such unauthorized modification, substitution, or attachment will be the responsibility of the user.

Welch Allyn Wireless Acquisition Module FCC ID: HJR-WAM2500
UTK FCC ID: HJR-UTK2500

Declaración de conformidad Mexico

La operación de este equipo está sujeta a las siguientes dos condiciones:

1. es posible que este equipo o dispositivo no cause interferencia perjudicial y
2. este equipo o dispositivo debe aceptar cualquier interferencia, incluyendo la que pueda causar su operación no deseada.

Industry Canada (IC) Emissions

RF Radiation Hazard Warning

Using higher gain antennas and types of antennas not certified for use with this product is not allowed. The device shall not be co-located with another transmitter.

Cet avertissement de sécurité est conforme aux limites d'exposition définies par la norme CNR-102 at relative aux fréquences radio.

This device complies with RSS 210 of Industry Canada.

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 this device.

L'utilisation de ce dispositif est autorisée seulement aux conditions suivantes: (1) il ne doit pas produire de brouillage et (2) l' utilisateur du dispositif doit étre prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe B est conform à la norme NMB-003 du Canada.

Welch Allyn Wireless Acquisition Module IC: 3758B-WAM2500
UTK : 3758B-UTK2500

European Union

Czech	Welch Allyn tímto prohlašuje, ze tento WLAN device je ve shodě se základními požadavky a dalšími příslušnými ustanoveními směrnice 2014/53/ES.
Danish	Undertegnede Welch Allyn erklærer herved, at følgende udstyr WLAN device overholder de væsentlige krav og øvrige relevante krav i direktiv 2014/53/EF
Dutch	Bij deze verklaart Welch Allyn dat deze WLAN device voldoet aan de essentiële eisen en aan de overige relevante bepalingen van Richtlijn 2014/53/EC.
English	Hereby, Welch Allyn, declares that this WLAN device is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EC.
Estonian	Käesolevaga kinnitab Welch Allyn seadme WLAN device vastavust direktiivi 2014/53/EÜ põhinõuetele ja nimetatud direktiivist tulenevatele teistele asjakohastele sätetele.
Finnish	Welch Allyn vakuuttaa täten että WLAN device tyyppinen laite on direktiivin 2014/53/EY oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.
French	Par la présente, Welch Allyn déclare que ce WLAN device est conforme aux exigences essentielles et aux autres dispositions de la directive 2014/53/CE qui lui sont applicables
German	Hiermit erklärt Welch Allyn die Übereinstimmung des Gerätes WLAN device mit den grundlegenden Anforderungen und den anderen relevanten Festlegungen der Richtlinie 2014/53/EG. (Wien)
Greek	ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ Welch Allyn ΔΗΛΩΝΕΙ ΟΤΙ WLAN device ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 2014/53/ΕΚ
Hungarian	Alulírott, Welch Allyn nyilatkozom, hogy a WLAN device megfelel a vonatkozó alapvetõ követelményeknek és az 2014/53/EC irányelv egyéb elõírásainak.
Italian	Con la presente Welch Allyn dichiara che questo WLAN device è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 2014/53/CE.
Latvian	Ar šo Welch Allyn deklarē, ka WLAN device atbilst Direktīvas 2014/53/EK būtiskajām prasībām un citiem ar to saistītajiem noteikumiem.
Lithuanian	Šiuo Welch Allyn deklaruoja, kad šis WLAN device atitinka esminius reikalavimus ir kitas 2014/53/EB Direktyvos nuostatas.
Malti	Hawnhekk, Welch Allyn, jiddikjara li dan WLAN device jikkonforma mal-htigijiet essenzjali u ma provvedimenti ohrajn relevanti li hemm fid-Dirrettiva 2014/53/EC
Portuguese	Welch Allyn declara que este WLAN device está conforme com os requisitos essenciais e outras disposições da Directiva 2014/53/CE.
Slovak	Welch Allyn týmto vyhlasuje, ze WLAN device spĺňa základné požiadavky a všetky príslušné ustanovenia Smernice 2014/53/ES.
Slovene	Šiuo Welch Allyn deklaruoja, kad šis WLAN device atitinka esminius reikalavimus ir kitas 2014/53/EB Direktyvos nuostatas.
Spanish	Por medio de la presente Welch Allyn declara que el WLAN device cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 2014/53/CE

Swedish	Härmed intygar Welch Allyn att denna WLAN device står I överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 2014/53/EG.

International Radio Compliance

Argentina	Ente Nacional de las Comunicaciones (ENACOM)	CNC COMISIÓN NACIONAL DE COMUNICACIONES H-22661 (WAM) H22622 (UTK)	
Australia	Australian Communications and Media Authority (ACMA) Radio Compliance Mark (RCM).		
Brazil	Agência Nacional de Telecomunicações (ANATEL)	 Modelo: WAM 01142-14-05187	Este equipamento opera em caráter secundário, isto é, não tem direito a proteção contra interferência prejudicial, mesmo de estações do mesmo tipo, e não pode causar interferência a sistemas operando em caráter primário.
EAC			Products meet all requirements of the corresponding technical regulations and have passed all conformity assessment procedures.
Indonesia	Keterangan a. [58975/SDPPI/2018] (UTK) adalah nomor sertifikat yang diterbitkan untuk setiap alat dan perangkat telekomunikasi b. [8260] (UTK) adalah nomor PLG ID (identitas pelanggan) berdasarkan database Lembaga Sertifikasi a. [60825/SDPPI/2019] (WAM) adalah nomor sertifikat yang diterbitkan untuk setiap alat dan perangkat telekomunikasi b. [8260] (WAM) adalah nomor PLG ID (identitas pelanggan) berdasarkan database Lembaga Sertifikasi	Identification a. [58975/SDPPI/2018] (UTK) is a number of certificate issued for certified telecommunication equipment b. [8260](UTK) is a number of PLG ID based on one Certification Body database a. [60825/SDPPI/2019] (WAM) is a number of certificate issued for certified telecommunication equipment b. [8260](WAM) is a number of PLG ID based on one Certification Body database	
Mexico	Instituto Federal de Telecomunicaciones (Federal Telecommunications Institute—IFETEL)	This product contains and Approved module, Model No. WAM, IFETEL No. RCPWEWA19-0527 This product contains and Approved module, Model No. UTK, IFETEL No. RCPWEUT19-0526	La operación de este equipo está sujeta a las siguientes dos condiciones: (1) es posible que este equipo o dispositivo no cause interferencia perjudicial y (2) este equipo o dispositivo debe aceptar cualquier interferencia, incluyendo la que pueda causar su operación no deseada.
Morocco		AUTHORIZED BY MOROCCO ANRT ***WAM**: Approval number:* MR 17489 ANRT 2018 *Date of approval:* 13-SEP-2018 ***UTK**: Approval number:* MR 17488 ANRT 2018	

		Date of approval: 13-SEP-2018
Oman	Telecommunications Regulatory Authority	WAM : R/6168/18 D172250 UTK: R/6164/18 D172250
Paraguay	Comisión Nacional de Telecomunicaciones	NR:121/2019 (WAM) NR:122/2019 (UTK)
Pakistan	Pakistan Telecom Authority	
Philippines	National Telecommunications Commission	**WAM**: ESD-18-18399C **UTK**: ESD-19-19449C
Singapore	Info-Communications Media Development Authority (IMDA)	Complies with IMDA Standards [DA105282]
South Korea	Korea Communications Commission (대한민 국 방송통 신위원 회) – KCC Certification number: **WAM**: IC MSIP-CRI-S83-WAM **UTK**: IC MSIP-CRI-S83-UTK	This equipment is Industrial (Class A) electromagnetic wave suitability equipment and seller or user should take notice of it, and this equipment is to be used in the places except for home. 이기기는업무용(A급)전자파적합기기로서 판매자 또는 사용자는 이 점을 주의하시기 바라 며, 가정외의지역에서사용하는것을 목적으로합니다. Class A Equipment (Industrial Broadcasting & Communication Equipment) A급기기(업무용방 송통신기자재)
South Africa	Independent Communications Authority of South Africa	WAM: TA = TA-2019/732 UTK: TA = TA-2019/731
UAE		**WAM**: ER65767/18 **UTK**: ER65804/18

INTRODUCTION

Manual Purpose

This manual is intended to provide the user with information about:

- Using and understanding the Welch Allyn Wireless Acquisition Module, the operator buttons, and the LED indicators.
- Preparing the Welch Allyn Wireless Acquisition Module for use.
- Acquiring and printing an ECG.
- Maintenance.

Audience

This manual is written for clinical professionals who are expected to have a working knowledge of medical procedures and terminology as required for monitoring and/or acquiring clinical data from cardiac patients.

Indications for Use

- Indicated for use as a radiofrequency physiological signal transmitter that acquires and delivers RF transmission of electrocardiographic data obtained during resting/physiologic electrocardiographic testing.
- Indicated for use in a clinical setting, by qualified medical professionals, properly trained for 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 involvements. It is not intended as a sole means of diagnosis.
- Indicated for use in hospital and physicians office, patients of any age where ECG acquisition is done (e.g., patients in Coronary Care Units, Step-Down Units, Emergency Departments, clinics, physicians offices, sports medicine facilities, or rehabilitation departments).
- It is not designed for use in highly invasive environments, such as an operating theatre.

System Description

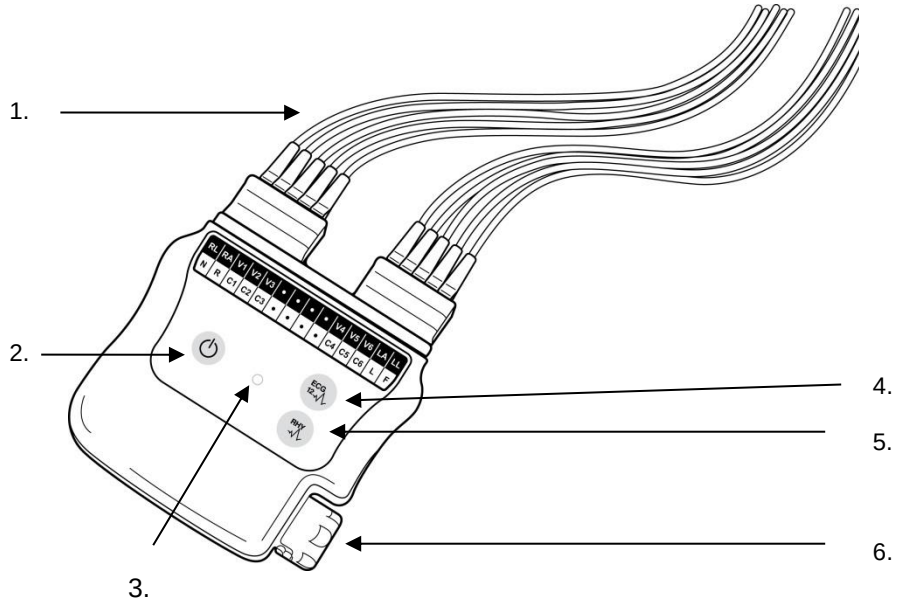
The Welch Allyn Wireless Acquisition Module incorporates wireless electrocardiographic technology to achieve the acquisition and RF transmission of diagnostic-quality 12-lead ECG data. Transmission of the ECG data to a receiver module allows the cardiac signals to be displayed on a monitoring device without the need for a direct connection.

The following equipment is necessary to use the Welch Allyn Wireless Acquisition Module:

- One AA alkaline battery, 1.5V
- UTK receiver module
- Lead wire sets
- ECG electrodes

Welch Allyn Wireless Acquisition Module with Lead Wires

Figure 1-1



No.	Feature	Description
1	Replaceable lead wires	Connector from the device to the electrode
2	Power On/Off	Push button to turn the device on and off
3	LED indicators	Displays the device status
4	12-lead ECG acquisition	Press the 12-lead ECG acquisition button to complete the acquisition of the 12-lead ECG
5	Rhythm print	Press to acquire a rhythm print; press again to stop the rhythm print
6	Battery compartment	Houses the alkaline battery

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 the Welch Allyn Diagnostic Cardiology Suite:

- Power On/Off
- Acquiring a 12-lead ECG

Note: Rhythm print button is non-functional when used with Welch Allyn Diagnostic Cardiology Suite.

Approved Battery Models

Description	Manufacturer	Part Numbers
Alkaline, AA-type, 1.5V	Various	Various

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

To order additional supplies, contact a customer service representative.

USB Transceiver Key (UTK)

The UTK connects to an open USB port on the computer where the Welch Allyn Diagnostic Cardiology Suite is installed and receives ECG signals from the paired WAM. When the UTK is connected to a USB cable from the PC port, it should be positioned in a location with an unobstructed view of the WAM while in use.

Pairing the Wireless Acquisition Module with the Welch Allyn Diagnostic Cardiology Suite

Open Welch Allyn Diagnostic Cardiology Suite ECG application and select Start a Resting Exam. Enter demographic information to go to the real-time display. Connect the UTK to an open USB port on the computer.

1. Select the settings icon in the upper right corner of the real-time display.
2. Select **WAM pairing**.
3. Place the Welch Allyn Wireless Acquisition Module (powered off) near the UTK receiver.
4. Select **Start** and then **Yes**.
5. Power on the acquisition module.

   When the device is successfully paired, message will display on screen accompanied by 3 beeps.
6. Select **Done**.

Note: The Welch Allyn Acquisition Module must be paired to a specific UTK prior to signal acquisition.

Battery Installation

The Welch Allyn Wireless Acquisition Module is powered with a single AA battery. When the battery contains sufficient voltage to operate and the patient is properly connected, an LED on the front of the device will appear solid green indicating proper pairing and communication with the UTK. A battery with low voltage or a lead fail will result in a flashing green or yellow LED.

To install a new battery, remove the battery cover by twisting the cover in a counterclockwise direction. Removal of the battery cover will automatically turn the power off. Insert one AA battery into the battery compartment aligning the battery's positive (+) and negative (-) indicators with the designators shown on the device's back label. Replace the battery cover by twisting the cover in a clockwise direction. The battery cover will seal the battery compartment and make contact with the battery providing power to the device.

Applying Power

Before you apply power to the Welch Allyn Wireless Acquisition Module, make sure that patient lead wires do not touch metal connected to ground (this may happen if reusable electrodes with exposed metal are used); the Welch Allyn Wireless Acquisition Module will auto-calibrate at power-on, and a large amount of noise caused by ground loops may disrupt calibration, in which case the ECG will not be displayed.

Press the power On/Off button. On initial startup, the LEDs will briefly flash yellow and green and the device will beep. LED status will indicate the following:

- Solid green: appropriate battery power level, good electrode-to-skin impedance, and good bidirectional communication with the UTK receiver module.
- Flashing green: low battery.
- Solid yellow: lead fail.
- Flashing yellow: low battery and/or lead fail.
- LED off: device not powered on, very low battery (no sound), or device out of range (device will beep intermittently).

Press the power On/Off button to turn the device off. An audible tone will sound indicating power off and RF disconnect.

Attaching the Lead Wire Connector Block

The 12-lead ECG lead wires consist of one connector block with 10 lead wires (5 leads wires to each side). The lead wires are positioned to follow the contour of the torso. Each lead wire terminates in a medi-clip or 4 mm banana connector.

Securely insert the connector block into the ECG input connector on the top of the device.


CAUTION: Be careful to insert the connector block into the appropriate input connector by matching the lead wire labels to the device label.

Labeling the Welch Allyn Wireless Acquisition Module and UTK

The Welch Allyn Wireless Acquisition Module ships with self-adhesive letters allowing the user to label it and its paired UTK. It is recommended these labels are applied to both the Welch Allyn Wireless Acquisition Module and its paired UTK to assist in keeping the units together.

Lead Fail

Lead fail is done automatically through visual communication with the LEDs located on the front of the device. 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 battery voltage for ECG acquisition.

LED Indicators

LED	+ Audio	MODE
GREEN off YELLOW off	Intermittent beeping	Device is on but not synched to a UTK and Welch Allyn Diagnostic Cardiology Suite ECG application. Follow the pairing process if necessary.
YELLOW solid or flashing GREEN off		Lead fail message, check leads for proper connection.
GREEN solid YELLOW off		No interaction required.
GREEN solid YELLOW off	Intermittent beeping	Device is collecting a 10-second ECG.
Flashing LED (yellow or green depending on lead fault status)		Replace AA battery.
GREEN off YELLOW off	1 second audio on, then device turns off.	Device has detected a very low battery status and powered off.

Use the LED indicators to check electrode-to skin impedance and verify patient hookup quality, as well as to ensure communication has been established with the UTK and the signal quality of each ECG is transmitted as expected. A yellow LED indicates a lead fail condition.

1. Ensure an AA battery is in the battery compartment. If battery voltage is too low, the device may not power on. Insert a new AA battery into the device to continue operation.
2. Press the On/Off button to turn the device on.
3. Connect the patient to the lead wires (see *Patient Hookup in the recording device user manual*).
4. ECG data should be automatically transmitted to the recording device.
5. Enter patient information at the recording device.
6. Press the 12-Lead ECG Acquisition button to complete the acquisition of the 12-lead ECG.
   ***NOTE**: During normal operation, the green LED will display continuously.*
   ***NOTE**: If the 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.*
7. At the end of the ECG acquisition session, the device should be turned off. ECG data may now be reviewed, plotted, or edited as needed using the Welch Allyn Diagnostic Cardiology Suite ECG application

MAINTENANCE

Check the Welch Allyn Wireless Acquisition Module and lead wires before each use to ensure they are not damaged or broken.

Cleaning and Disinfecting the Welch Allyn Wireless Acquisition Module

1. Remove all lead wires and the power source from the device before cleaning.

2. For general cleaning, use a soft, lint-free cloth lightly moistened with a mild soap and water solution. Wipe and air dry.

3. For disinfecting, wipe exterior with a soft, lint-free cloth using:

   Clorox Healthcare ® Bleach Germicidal Wipes (use according to instructions on product label), *or*

   A soft, lint-free cloth with a solution of Sodium Hypochlorite (10% household bleach and water solution) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution as recommended by the APIC Guidelines for Selection and Use of Disinfectants.

4. Use caution with excess liquid as contact with metal parts may cause corrosion.

5. Do not immerse lead wires; immersion can cause metal corrosion.

6. Do not use excessive drying techniques such as forced heat.

***WARNING**: Prevent liquid from penetrating the device and do not attempt to clean/disinfect the device or lead wires by submerging into a liquid, autoclaving, or steam cleaning. Never expose lead wires to strong ultra-violet radiation. Do not sterilize the device or patient cables with Ethylene Oxide (EtO) gas.*

Disposal of Waste Materials

Observe separate collection of electrical and electronic equipment. Do not dispose as unsorted municipal waste. Follow local disposal and recycling procedures.

APPENDIX

Part Numbers

Description	Part Numbers
WAM CC ACCESSORY KIT WITH AHA BANANA LEADS	41000-031-54
WAM CC ACCESSORY KIT WITH IEC BANANA LEADS	41000-031-55
WAM CC ACCESSORY KIT WITH AHA CLIP LEADS	41000-031-56
WAM CC ACCESSORY KIT WITH IEC CLIP LEADS	41000-031-57
BATTERY CAP ASSEMBLY WAM	8356-008-51
COMBINER WAM LEADS 10 POSITION IEC & AHA GRAY	9293-046-07
RPLCE LD SET WAM/AM12 FULL SET BANA AHA GRAY	9293-046-60
RPLCE LD SET WAM/AM12 FULL SET BANA IEC GRAY	9293-046-61
RPLCE LD SET WAM/AM12 LIMBS BANA AHA GRY	9293-046-62
RPLCE LD SET WAM/AM12 LIMBS BANA IEC GRY	9293-046-63
RPLCE LD SET WAM/AM12 V1-V3 BANA AHA GRY	9293-046-64
RPLCE LD SET WAM/AM12 C1-C3 BANA IEC GRY	9293-046-65
RPLCE LD SET WAM/AM12 V4-V6 BANA AHA GRY	9293-046-66
RPLCE LD SET WAM/AM12 C4-C6 BANA IEC GRY	9293-046-67
RPLCE LD SET WAM/AM12 FULL SET CLIP AHA GRAY	9293-047-60
RPLCE LD SET WAM/AM12 FULL SET CLIP IEC GRAY	9293-047-61
RPLCE LD SET WAM/AM12 LIMBS CLIP AHA GRY	9293-047-62
RPLCE LD SET WAM/AM12 LIMBS CLIP IEC GRY	9293-047-63
RPLCE LD SET WAM/AM12 V1-V3 CLIP AHA GRY	9293-047-64
RPLCE LD SET WAM/AM12 C1-C3 CLIP IEC GRY	9293-047-65
RPLCE LD SET WAM/AM12 V4-V6 CLIP AHA GRY	9293-047-66
RPLCE LD SET WAM/AM12 C4-C6 CLIP IEC GRY	9293-047-67
LEAD SET WAM/AM12 10-WIRE SHORT CLIPS AHA GRAY	9293-047-70
LEAD SET WAM/AM12 10-WIRE SHORT CLIPS IEC GRAY	9293-047-71
RPLCE LEAD SET WAM/AM12 LIMBS SHORT CLIPS AHA GRAY	9293-047-72
RPLCE LEAD SET WAM/AM12 LIMBS SHORT CLIPS IEC GRAY	9293-047-73
RPLCE LEAD SET WAM/AM12 V1-V3 SHORT CLIPS AHA GRAY	9293-047-74
RPLCE LEAD SET WAM/AM12 C1-C3 SHORT CLIPS IEC GRAY	9293-047-75
RPLCE LEAD SET WAM/AM12 V4-V6 SHORT CLIPS AHA GRAY	9293-047-76
RPLCE LEAD SET WAM/AM12 C4-C6 SHORT CLIPS IEC GRAY	9293-047-77
WIRELESS ACQUISITION MODULE AND UTK USER MANUAL	9515-174-60

Welch Allyn Wireless Acquisition Module Specifications

Feature	Specification*
Instrument Type	12-lead wireless acquisition module for resting ECG
Input Channels	12-lead signal acquisition and transmission
ECG Leads Transmitted	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6
Transmission Protocol	Bidirectional and frequency hopping; beacon and response method links a single acquisition module to a single UTK receiver module
Frequency Range	2403.38 MHz to 2479.45 MHz
Channel spacing	1MHz
RF output power	<10dBm
Antenna Type	PCB inverted F
Antenna Gain	-0.33dBi
Modulation	MSK
Receiver Distance	Approximately 10 feet (3 meters)
Lead Set	RA, LA, RL, LL, V1, V2, V3, V4, V5, and V6 (R, L, N, F, C1, C2, C3, C4, C5, and C6) with detachable lead wires
Sampling Rate	40,000 samples/second/channel acquisition; 1,000 samples/second/channel transmitted for analysis
Resolution	1.875 microvolt LSB
User Interface	Three-button operation: ON/OFF, 12-lead ECG acquisition, and rhythm strip acquisition
Defibrillator Protection	Complies with AAMI standards and IEC 60601-2-25
Special Functions	LED indication of power status, operating mode, lead fail, and remaining battery charge
Device Classification	Type CF, battery operated
Weight	6.7 oz. (190 g) with battery
Dimensions	4.45 x 4.25 x 1.1” (11.3 x 10.8 x 2.79 cm)

Battery	1 AA alkaline battery typically powers the device for acquisition of 250 resting ECGs

**Specifications subject to change without notice.*

UTK Specifications

Feature	Specification
Frequency	2403.38 MHz to 2479.45 MHz
Channel spacing	1MHz
RF output power	<10dBm
Antenna Type	PCB inverted F
Antenna Gain	-4.12dBi
Modulation	MSK

* Specifications subject to change without notice.

Serial and Part Number Location

For questions and service information, have both serial and part number available when calling.

The model type, serial number (SN), and part number (REF) are found on the back label of the device.