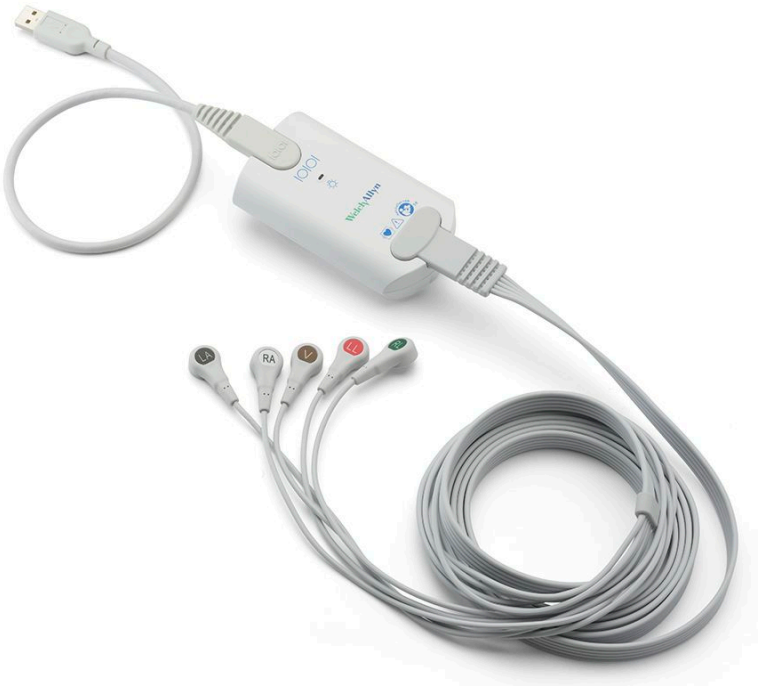
Hillrom™

Welch Allyn® Connex® Devices ECG Module



Instructions for use

For use with compatible Connex® devices running software version 2.3X or higher

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REF 80024036 Ver. C

REF 6000-ECG3I, 6000-ECG3A, 6000-ECG5I, 6000-ECG5A

Revision date: 2021-07

This manual applies to # 901106 ECG Plug-in module, 901060 Vital Signs Monitor, and 901028 Vital Signs Monitor Wall System.

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Contents

Introduction

This manual describes the capabilities and operation of the Welch Allyn ECG/Impedance Respiration module. This module is designed as an option for the Welch Allyn Connex® Vital Signs Monitor (VSM) and the Connex® Integrated Wall System (IWS). This module might not be available in your region.

When connected to the Connex VSM or the Connex IWS, the module supports the measurement and continuous display of 3- or 5-lead ECG waveforms, ECG heart rate readings, and ECG impedance respiration readings. The module also provides optional pacemaker and arrhythmia detection (ventricular tachycardia, ventricular fibrillation, and asystole), as well as associated technical and physiological alarms.

Before using the ECG module, read this manual as well as the sections of the *Welch Allyn Connex® Devices Instructions for use* that pertain to your use of the module.

Intended use

CAUTION United States Federal law restricts this device to sale, distribution, or use by or on the order of a physician or licensed healthcare professional.

The ECG/Impedance Respiration module is intended for continuous measurement of respiration rate, heart rate, and detection of cardiac standstill (asystole), ventricular tachycardia, and ventricular fibrillation in general medical and surgical floors, general hospital and alternate professional healthcare environments. The system is indicated for use in pediatric and adult patients.

Indications for use

The Welch Allyn ECG/Impedance Respiration module and associated software acquires and analyzes ECG signals from patients. Patients are people with coronary problems, suspected coronary problems, or recent medical procedures that require cardiac monitoring.

This ECG module can be used on adult and pediatric patients.

The ECG module is indicated for use by healthcare professionals whenever there is a need to monitor a patient's physiological parameters for the following:

- ECG
- ECG with alarms for ventricular tachycardia, ventricular fibrillation, and asystole
- Impedance respiration

Contraindications

The Welch Allyn ECG/Impedance Respiration module is not intended for infants weighing less than 10 Kg (22 lbs) or neonatal patients.

This module is not designed for direct cardiac application.

This module is not suitable for transport.

Computer-assisted ECG data acquisition and interpretation is a valuable tool when used properly. However, no automated interpretation is completely reliable. Interpretations should be reviewed by a qualified physician before treatment, or non-treatment, of any patient.

Symbols

For information on the origin of these symbols, see the Welch Allyn symbols glossary: https://www.hillrom.com/content/dam/hillrom-aem/us/en/sap-documents/LIT/80022/80022945LITPDF.pdf.

Documentation symbols

	**WARNING** The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death.
	**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. This definition applies to both yellow and black and white symbols.
	Follow directions/instructions for use (IFU) — mandatory action. A copy of the IFU is available on this website. A printed copy of the IFU can be ordered from Welch Allyn for delivery within 7 days.

Miscellaneous symbols

	USB	**IOIOI**	Serial interface
	LED status indicator No LED: Off, not powered Steady green: Powered Flashing green: Powered, enumerated, sending patient data Steady yellow: Powered, internal error or POST	**R_x ONLY**	Prescription only or "For Use by or on the order of a licensed medical professional"

	Manufacturer		Date of manufacture
	Separate collection of Electrical and Electronic Equipment. Do not dispose as unsorted municipal waste.		China RoHS markings for control of pollution caused by electronic information products. XX indicates Environmentally Friendly Use Period in years.
	Product Identifier		Serial number
	Reorder Number		Global Trade Item Number
	Defibrillation-proof Type CF applied parts		Consult the manual

Screen elements

ECG, Heart rate/Pulse rate, and Impedance respiration			
			ECG frame and lead selector
	Heart rate / Pulse rate		Beats per minute (to represent heart rate / pulse rate)
	Saved waveform icon (Review tab)		Saved waveform icon, alarm condition (Review tab)
	Waveform snapshot button		

About warnings and cautions

Warning and caution statements can appear on the ECG module, on the packaging, on the shipping container, or in this document.

The ECG/Impedance Respiration module is safe for patients and clinicians when used in accordance with the instructions and the warning and caution statements presented in this manual.

Before using the module, you must familiarize yourself with all warnings and cautions and with the sections of this instructions for use that pertain to your use of the module. In addition, you must review the warnings and cautions presented in the *Welch Allyn Connex® Devices Instructions for use* that pertain to using a connected ECG module.

- Failure to understand and observe any warning statement in this manual could lead to patient injury, illness, or death.
- Failure to understand and observe any caution statement in this manual could lead to damage to the equipment or other property, or loss of patient data.

General warnings and cautions

WARNING Many environmental variables, including patient physiology and clinical application, can affect the accuracy and performance of the Connex device and ECG module. Therefore, you must verify all vital signs information before treating the patient. If there is any question about the accuracy of a measurement, verify the measurement using another clinically accepted method.

WARNING To comply with Federal Communications Commission (FCC) RF exposure requirements and to avoid exposure to radio-frequency (RF) radiation, always use the monitor in accordance with the operating conditions and instructions provided in this manual.

WARNING Always check the patient mode (adult, pediatric, or neonate) when monitoring a new patient. The patient mode determines default alarm limits and internal algorithm settings. Alarm limits are patient-specific. Make sure the monitor has settings that are appropriate before monitoring the patient. For alarms to function properly, you must set or verify alarm limits appropriate for each patient. Each time the Connex device is powered on, you must check that the alarm settings are appropriate for your patient before you start monitoring.

WARNING The Connex device and ECG module might not meet their performance specifications if stored or used outside the specified temperature and humidity ranges.

WARNING Use only Welch Allyn approved accessories, and use them according to the manufacturer's instructions for use. Using unapproved accessories with the monitor can affect patient and operator safety and can compromise product performance and accuracy.

WARNING Inaccurate measurement risk. Do not connect more than one patient to a Connex device.

WARNING Inaccurate measurement risk. Liquids and excessive moisture can damage patient sensors and cause them to perform inaccurately or fail.

WARNING Patient harm risk. Always remove sensors from patients and disconnect them completely from Connex devices before bathing.

WARNING Safety risk and potential shock hazard. Cords, cables, and accessories damaged from prior misuse can affect patient and operator safety. Inspect all cords, cables, and accessories for strain relief wear, fraying, or other damage according to the recommendations presented in the Maintenance and service section of this manual. Replace as necessary. Inspect the AC cord for exposed copper before touching the cord. Unplug the AC cord only by pulling on the plug, never the cord. Never lift the Connex device by the power cord or patient connections. Never lift the ECG module by the USB cable or the patient cable.

WARNING The ECG module may not function properly if dropped or damaged. Protect it from severe impact and shock. Do not use the ECG module if you notice any signs of damage. Qualified service personnel must check any ECG module that is dropped or damaged for proper operation before putting the device back into use.

WARNING Electric shock hazard. Do not open the ECG module. Do not attempt repairs. The ECG module has no user-serviceable internal parts. Only perform routine cleaning and maintenance procedures specifically described in this manual.

WARNING Use the ECG module only as described in this instructions for use. Do not use the ECG module on patients as described in the Contraindications.

WARNING Personal/patient injury risk. Wall-mounted equipment and accessories must be installed in accordance with accompanying instructions. Improper installation can result in the equipment falling off the wall and injuring someone. Welch Allyn is not responsible for the integrity of any installation not performed by authorized Welch Allyn service personnel. Contact an authorized Welch Allyn service representative or other qualified service personnel to ensure professional installation for safety and reliability of any mounting accessory.

WARNING Personal/patient injury and equipment damage risk. Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation. When transporting the Connex device and ECG module on a mobile stand, properly secure all patient cables and cords to keep them clear of the wheels and to minimize trip hazards for patients and clinicians.

WARNING For operator and patient safety, peripheral equipment and accessories that can come in direct patient contact must comply with all applicable safety, EMC, and regulatory requirements.

WARNING Cross-contamination or nosocomial infection risk. Clean and disinfect the ECG module on a routine basis according to your facility's protocols and standards or local regulations. Thorough hand-washing before and after contact with patients greatly reduces the risk of cross-contamination and nosocomial infection.

WARNING For patient safety, do not use the device or any accessory during MRI scanning. Induced current could cause burns.

WARNING Do not pause or turn off an audible alarm if the patient safety might be compromised.

CAUTION United States Federal law restricts this equipment to sale, distribution, or use by or on the order of a physician or licensed healthcare professional.

CAUTION Electromagnetic interference risk. The equipment complies with applicable domestic and international standards for electromagnetic interference. These standards are intended to minimize medical equipment electromagnetic interference. Although the Connex device and ECG module are not expected to present problems to other compliant equipment or be affected by other compliant devices, interference issues still may occur. As a precaution, avoid using the equipment in close proximity to other equipment. In the event that equipment interference is observed, relocate the equipment as necessary or consult manufacturer's instructions for use.

CAUTION Keep the Connex device outside of MRI suites and any areas marked for high magnetic or electric field strength.

ECG module warnings and cautions

In addition to the preceding warnings and cautions, consider the following when using the ECG module.

WARNING Liquids can damage electronics inside the ECG module. Prevent liquids from spilling on the ECG module.

If liquids are spilled on the ECG module, remove it from service.

Note The module provides no protection against liquid ingress.

WARNING Do not operate the Connex device and ECG module near equipment that emits strong electromagnetic or radio-frequency signals. Electronic equipment of this type can cause electrical interference with device operation, which can distort the ECG signal and prevent accurate rhythm analysis.

WARNING Patient safety risk. Life-threatening arrhythmias can trigger one of two optional high alarm tones for ventricular tachycardia (V-Tach), ventricular fibrillation (V-Fib), and asystole. If you are monitoring a patient for life-threatening arrhythmias, verify the alarm tone that your facility or floor has chosen.

WARNING Patient injury risk. Do not perform waveform analysis on the ECG acquisition display as these ECG representations are not true to scale. Make manual measurements of ECG intervals and magnitudes on printed ECG reports only.

WARNING The arrhythmia analysis program is intended to detect V-Tach, V-Fib, and asystole. It is not intended to detect other arrhythmias. Occasionally it may incorrectly identify the presence or absence of an arrhythmia. Therefore a physician must analyze the arrhythmia information in conjunction with other clinical findings.

WARNING Arrhythmia detection (for V-Tach, V-Fib, and asystole) and impedance respiration are not intended for neonatal patients.

WARNING Computer-assisted ECG data acquisition and interpretation is a valuable tool when used properly. However, no automated interpretation is completely reliable and a qualified physician shall review the interpretations before treatment, or non-treatment, of any patient. The ECG module must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment. Certain arrhythmias or pacemaker signals could adversely affect heart rate indications or alarms.

WARNING Patient injury risk. The data captured from this device should not be used as a sole means for determining a patient's diagnosis or prescribing treatment.

WARNING Physiological variations in the patient population generate a nearly infinite range of possible ECG waveform morphologies. In some cases, the Connex device occasionally may not alarm or alarm inappropriately for some arrhythmia (V-Tach, V-Fib and asystole) waveforms. It is the operator 's responsibility to set alarm limits as appropriate for each individual patient. High risk patients must be kept under close surveillance.

WARNING For patients with a pacemaker, maintain a minimum of 6 inches between the device and pacemaker. Power down the ECG module immediately and provide appropriate patient care if you suspect the ECG module has affected the pacemaker.

WARNING Patient safety risk. Use of impedance respiration monitoring can affect the operation of some pacemakers. Keep pacemaker patients under close observation. If pacemaker operation is affected, turn off impedance respiration.

WARNING Impedance respiration must be disabled when using ECG wrist clip electrodes.

WARNING Inaccurate measurement risk. Impedance respiration monitoring is not reliable when ECG electrodes are placed on the limbs.

WARNING Patient safety risk. Correctly set pacemaker detection and keep pacemaker patients under close observation. A pacemaker pulse can be counted as a QRS, which could result in an incorrect heart rate and failure to detect cardiac arrest and some life-threatening arrhythmias (V-Tach, V-Fib, and asystole). If your patient has a pacemaker, turn pacemaker detection ON to avoid this hazard.

WARNING Inaccurate measurement risk. When an external pacemaker is being used on a patient, arrhythmia monitoring (to detect V-Tach, V-Fib and asystole) is severely compromised due to the high energy level in the pacemaker pulse. This may result in the arrhythmia algorithm's failure to detect pacemaker non-capture or asystole.

WARNING Patient safety risk. Implantable pacemakers, which are minute-ventilation-rate adaptive, can occasionally interact with the impedance respiration measurement of cardiac monitors causing the pacemakers to pace at their maximum. Keep pacemaker patients under close observation.

WARNING Inspect device and accessories before each use. Use only Welch Allyn approved accessories. Peripheral equipment and accessories that touch the patient must comply with all appropriate safety, EMC, and regulatory requirements.

WARNING Frequently inspect—electrically and visually—all cables, sensors, and electrode wires. Replace any damaged cables, sensors, or wires. Failure to properly inspect and keep in excellent working order all cables, sensors, and electrode wires can result in hazards to patients and to equipment failure and damage.

WARNING Always keep patient motion to a minimum. Motion artifact can cause inaccurate measurement of patient vital signs.

WARNING The conductive parts of electrodes and associated connectors for type BF or CF applied parts, including neutral electrode, should not contact other conductive parts including earth.

WARNING Skin irritation may result from the continuous application of the ECG electrodes. Examine the skin for signs of irritation or inflammation and avoid placing the electrode in those areas. If you observe skin irritation, replace the electrodes or change the location of the electrodes every 24 hours.

WARNING Connect patient lead wires only to the patient electrodes.

WARNING Patient safety risk. The most important aspect of obtaining a quality electrocardiogram is a proper electrode hook-up. Failure to properly apply the electrodes and patient cable may result in noisy signal, false alarms, or sub-optimal electrocardiogram analysis, which could cause patient harm. Any of these events could potentially contribute to patient harm.

WARNING Patient injury risk. Use only accessories approved by Welch Allyn, including electrodes, lead wires, and patient cables. These approved accessories are required for electrical protection of the patient during cardiac defibrillation. Refer to the accessory list or visit the Hillrom Parts Store https://parts.hillrom.com/.

WARNING Patient injury risk. Use only ECG cables supplied or specified by Welch Allyn. Use of any other ECG cables can negate defibrillator protection and can create a risk of patient injury due to shock.

WARNING To avoid serious injury or death, take precautions consistent with good clinical practice during patient defibrillation:

- Avoid contact with the electrocardiograph, patient cable, and patient.
- Place defibrillator paddles properly in relation to electrodes.

WARNING To avoid serious injury or death, take precautions consistent with good clinical practice during patient defibrillation:

- Before defibrillation, verify that patient leads are properly connected to the patient and the ECG module. Loose ECG leads can divert defibrillator current.
- After defibrillation, pull each patient lead out of the patient cable and inspect the tips for charring (black carbon marks). If there is any charring, the patient cable and individual leads must be replaced. If there is no charring, fully reinsert the leads into the patient cable. (Charring can occur only if a lead is not fully inserted into the patient cable before defibrillation.)

WARNING Electric shock hazard. Before cleaning the monitor, disconnect the AC power cord from the mains outlet and the power source.

WARNING This equipment must not be connected to any other equipment that is not compliant with EN60601-1. The combined leakage currents could exceed safe limits.

WARNING Use of accessories, transducers, and cables other than those specified may result in degraded electromagnetic compatibility performance of this device.

WARNING Do not operate this product with MRI (Magnetic Resonance Imaging) equipment.

WARNING When using ECG Wrist Clip electrodes, although a normal Lead I QRS waveform is produced on the monitor, this waveform should not be used for serious clinical interpretation because the electrodes are not properly triangulated around the patient 's heart.

WARNING Inaccurate measurement risk. To use ECG wrist clip electrodes effectively, consider the following:

- The size of ECG wrist clip electrodes is fixed; you cannot adjust it.
- Proper orientation of the clip with the monitor depends on repositioning the clip until you achieve a snug fit.
- The preferred position of the clip is the patient's wrist, but you can move it up the patient's arm toward the torso.
- The clip might not work with patients who have small wrists and arms.
- Exercise caution when placing the clip so that it doesn't impede circulation along the patient's wrist and arm.
- If you cannot achieve a snug fit with the wrist clip, use some other method to monitor ECG.

WARNING Do not pause or turn off an audible alarm if the patient safety might be compromised.

WARNING Always ensure that the appropriate electrode placement is employed for the lead configuration selected.

WARNING The ECG module should not be used on patients who are linked to heart lung machines.

WARNING If an electrosurgical unit is used, place the ECG cable and wires as far as possible from the site of the surgery and from the electrosurgical cables. This will minimize interference and the risk of burns to the patient. Ensure that the electrosurgical return cable (neutral) is well attached and making good contact with the patient.

WARNING Patient injury risk. To prevent cross-contamination and the spread of infection:

- Dispose of single-patient use components (for example, electrodes) after use.
- Regularly clean and disinfect all components that come in contact with patients.
- Reprocess the device accessories (for example, patient cable, leads, and reusable electrodes) between patients.

WARNING Personal /patient injury risk. Wall-mounted equipment and accessories must be installed in accordance with accompanying instructions. Improper installation can result in the equipment falling off the wall and injuring someone.

WARNING Personal/patient injury risk. Wall Mount must be mounted using the appropriate hardware for the type of wall structure. Your facility may need to provide the appropriate hardware needed to install for your type of wall structure.

WARNING Personal/patient injury risk. Wall Mounts must be installed by authorized Welch Allyn service personnel or a Biomedical engineer to ensure mounting integrity and proper placement.

WARNING Personal/patient injury risk. Only authorized Welch Allyn service personnel or a Biomedical engineer should attach or remove the device from the wall mount.

WARNING Personal/patient injury risk. Any modification made to a Welch Allyn mounting solution removes Welch Allyn from responsibility or liability and voids the warranty.

WARNING Personal/patient injury risk. Welch Allyn is not responsible for the integrity of any installation not performed by authorized Welch Allyn service personnel.

WARNING Personal/patient injury risk. Welch Allyn is not responsible for the integrity of any wall structure or wall mounting interface. Welch Allyn recommends that you contact your Biomedical Engineering Department or maintenance service to ensure professional installation, safety, and reliability of any mounting accessory.

CAUTION Position the wall mount so that the screen, controls, and connectors are accessible and support optimal and ergonomic use of the device.

CAUTION Never use acetone, ether, freon, petroleum derivatives, or other solvents to clean the ECG Module. Never immerse the ECG module or the patient cable in liquid. Never autoclave or steam clean the ECG module or the patient cable. Never pour alcohol directly on the ECG module or the patient cable, and never soak any components in alcohol. If any liquid enters the ECG module, remove the ECG module from service, and have it inspected by a qualified service person before using it again.

CAUTION Verify that dates on applicable accessories have not expired.

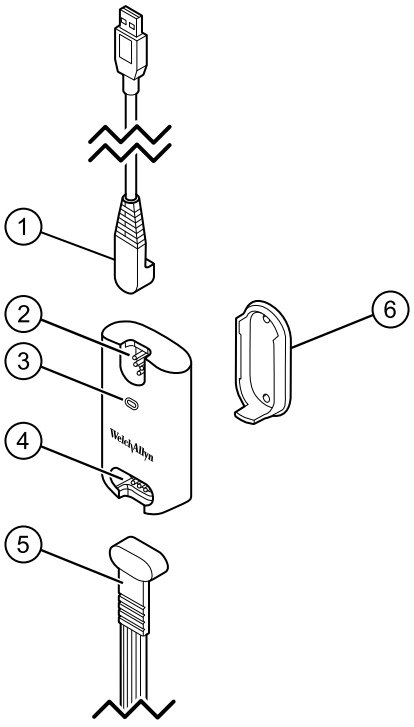
CAUTION Connect the USB cable to the Connex device in a manner that minimizes entangling.

CAUTION To prevent accidental loosening of the USB cable and the potential loss of ECG connection to the device, you must close the door and tighten the screw to secure the cable in place.

Setup

Controls, indicators, and connectors

The ECG/Impedance respiration assembly includes the ECG acquisition module, an ECG patient cable with either 3 or 5 leads to snap connectors, a built-in clip to facilitate mounting the module, and a USB cable to connect to the host device.



No.	Feature	Description
1	USB cable	Connects module to the Connex Vital Signs Monitor; provides power to the ECG module and supports data transmission between the module and monitor
2	USB cable connector	Provides connection for a USB cable to power the module and transmit data between the module and the monitor

No.	Feature	Description
3	LED module status indicator	Indicates to module status as follows: • No LED: Off, not powered • Steady green: Powered • Flashing green: Powered, enumerated, sending patient data • Steady yellow: Powered, internal error or POST
4	ECG patient cable connector	Provides connection for an ECG patient cable with either 3 or 5 leads to snap connectors
5	ECG patient cable	Connects to the module and to either 3 or 5 leads to snap connectors
6	Mounting clip	Provides the surface onto which the back of the module slides to mount the module on a bin or basket

Mount and connect the ECG module

To mount the ECG module on the desired mounting apparatus (basket, bin, wall mount), follow the instructions presented in the "Connex® Devices ECG Module Assembly Instructions" packaged with the module.

CAUTION Mount the ECG module before use. Position the module as instructed using only the provided mounting fixture. Any other mounting position or setup will compromise water ingress protection.

CAUTION Connect the USB cable to the Connex device in a manner that minimizes entangling.

CAUTION To prevent accidental loosening of the USB cable and the potential loss of ECG connection to the device, you must close the door and tighten the screw to secure the cable in place.

CAUTION Accessories attached to this device must run on battery power. Do not use any accessory's external power supply when it is attached to the monitor.

NOTE On some stands, the mounting bracket partially overlaps the USB door. If you observe this overlap, loosen the screw on the mounting bracket and shift the device forward just enough on the bracket to open the USB door, then slide the device back on the mounting bracket.

NOTE If you loosened the mounting bracket in order to open the USB door, shift the device forward on the bracket, close the door, and then slide the device back into its mounted position. Ensure that the device is seated firmly on the bracket, then tighten the screw on the bracket into the screw hole on the back of the device. (See "Mount the monitor on a stand" in the *Welch Allyn Connex® Devices Instructions for use* for more detail.)

Alarms

The Connex device displays physiological and technical alarms triggered by the ECG/ Impedance Respiration module. Physiological alarms occur when vital sign measurements fall outside of set alarm limits. Technical alarms occur when there is the problem with the module, an accessory connected to the module, the Connex device, or the network. The module can communicate alarms to the monitor and an external Nurse Call, if available, in the Continuous Monitoring profile. Technical alarms occur in all profiles.

See the *Welch Allyn Connex® Devices Instructions for use* for detailed descriptions of alarm behavior, controls, and messages.

Physiological alarm summary

Alarm condition	Alarm threshold
Asystole	No detectable beat for ≥4 seconds
Ventricular tachycardia	Default: 120 bpm ±3 bpm for 6 consecutive beats Range: 100 to 150 bpm ±3 bpm for 6 consecutive beats
Ventricular fibrillation	Fibrillatory waveform persisting for ≥4 seconds
Heart rate	Heart rate above high rate alarm or below low rate alarm threshold
Impedance respiration rate	Respiration rate above high rate or below low rate alarm threshold

Alarm limits	Upper limit range of entry	Lower limit range of entry
Ventricular tachycardia	150 beats per minute	100 beats per minute
Heart rate	300 beats per minute	20 beats per minute
Impedance respiration rate	100 breaths per minute	5 breaths per minute

ECG acquisition

For details on how the ECG module operates with the host device, see the ECG section of the *Welch Allyn Connex® Devices Instructions for use*.

Lead placement overview

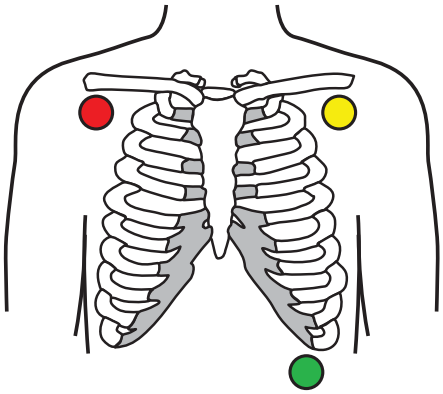
WARNING Patient safety risk. To minimize interference and the danger of burns to the patient, use only approved ECG cables. Keep the ECG cable as far away as possible from any electrosurgical cables. Make sure that the electrosurgical return conductor (neutral) is properly attached to the patient and makes a good contact.

Proper lead placement is important for a successful ECG. The most common ECG problems are caused by poor electrode contact and loose leads.

The following table shows the relationships between IEC and AHA leads as well as their placement.

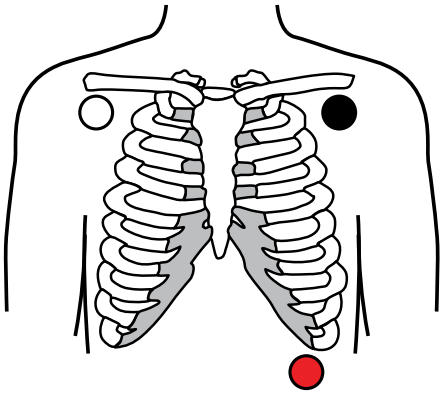
IEC Lead	IEC Color	AHA Lead	AHA Color	Placement
R	Red	RA	White	Right arm
L	Yellow	LA	Black	Left arm
F	Green	LL	Red	Left leg
C or C1	White	V or V1	Brown	4th intercostal (IC) space at right border of the sternum
N	Black	RL	Green	Right leg

Lead placement, 3-lead



IEC

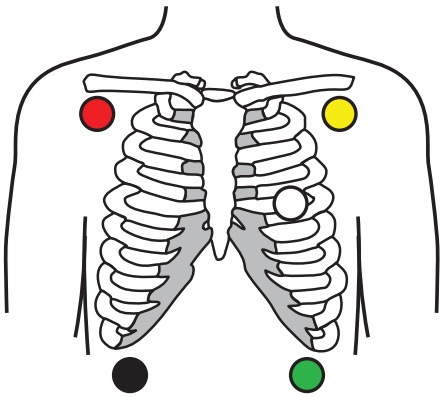
R - Red
L - Yellow
F - Green



AHA

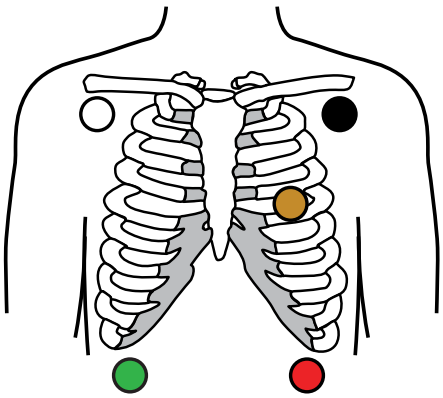
RA - White
LA - Black
LL - Red

Lead placement, 5-lead



IEC

N - Black
R - Red
L - Yellow
C - White
F - Green



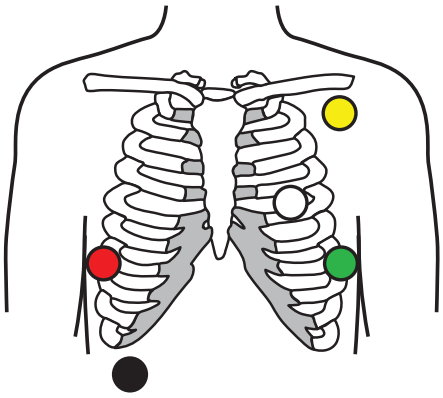
AHA

RL - Green
RA - White
LA - Black
V - Brown
LL - Red

Impedance respiration

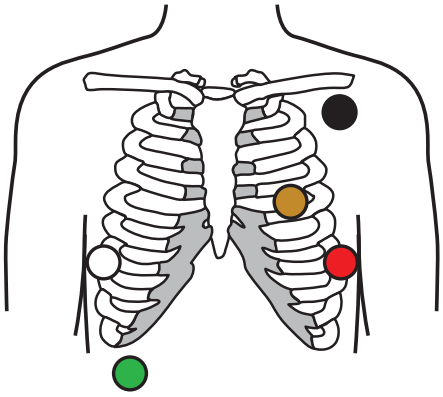
In some patients, impedance respiration detection may be inadequate using the standard ECG electrode placement. In these cases, change the LL and RA electrode placement to the mid-axillary line on each side of the chest as shown in the illustrations.

NOTE Respiration can only be acquired from Lead II.



IEC

N - Black
R - Red
L - Yellow
C - White
F - Green



AHA

RL - Green
RA - White
LA - Black
V - Brown
LL - Red

Attach the leads to the patient

Proper lead attachment is important for a successful ECG. The most common ECG problems are caused by poor electrode contact and loose leads. Follow your local procedures for attaching the leads to the patient. Here are some common guidelines.

WARNING Electrodes can cause allergic reactions. To avoid this, follow the electrode manufacturer's instructions.

WARNING Skin irritation may result from the continuous application of the ECG electrodes. Examine the skin for signs of irritation or inflammation and avoid placing the electrode in those areas. If you observe skin irritation, replace the electrodes or change the location of the electrodes every 24 hours.

WARNING Connect patient lead wires only to the patient electrodes.

WARNING Patient safety risk. The most important aspect of obtaining a quality electrocardiogram is a proper electrode hook-up. Failure to properly apply the electrodes and patient cable may result in noisy signal, false alarms, or sub-optimal electrocardiogram analysis, which could cause patient harm. Any of these events could potentially contribute to patient harm.

WARNING Patient injury risk. Use only accessories approved by Welch Allyn, including electrodes, lead wires, and patient cables. These approved accessories are required for electrical protection of the patient during cardiac defibrillation. Refer to the accessory list or visit the Hillrom Parts Store https://parts.hillrom.com/.

WARNING Inaccurate measurement risk. Impedance respiration monitoring is not reliable when ECG electrodes are placed on the limbs.

WARNING When using ECG Wrist Clip electrodes, although a normal Lead I QRS waveform is produced on the monitor, this waveform should not be used for serious clinical interpretation because the electrodes are not properly triangulated around the patient 's heart.

WARNING Inaccurate measurement risk. To use ECG wrist clip electrodes effectively, consider the following:

- The size of ECG wrist clip electrodes is fixed; you cannot adjust it.
- Proper orientation of the clip with the monitor depends on repositioning the clip until you achieve a snug fit.
- The preferred position of the clip is the patient's wrist, but you can move it up the patient's arm toward the torso.
- The clip might not work with patients who have small wrists and arms.
- Exercise caution when placing the clip so that it doesn't impede circulation along the patient's wrist and arm.
- If you cannot achieve a snug fit with the wrist clip, use some other method to monitor ECG.

WARNING Respiration Rate must be disabled when using ECG wrist clip electrodes.

To attach the leads to the patient

1. Prepare the patient.
   - Describe the ECG procedure. Explain the importance of holding still during the test. (Movement can create artifact.)
   - Verify that the patient is comfortable, warm, and relaxed. (Shivering can create artifact.)
   - Put the patient in a supine position.

2. Prepare the electrode locations.
   - Shave and gently abrade the areas where you will place the electrodes. Take care not to compromise skin integrity.
   - Thoroughly clean the skin, and lightly rub it dry. You may use soap and water, isopropyl alcohol, or skin preparation pads.
3. Confirm that the patient cable is attached to the module, and then snap the lead wire to each the electrode.
4. Apply the electrodes (disposable or reusable) to the patient according to the "Lead placement overview" presented earlier in this section.
   - **For reusable electrodes**: Use electrode paste, gel, or cream to cover an area the size of each electrode but no larger.

     NOTE Check for buildup of materials on reusable electrodes which can reduce waveform quality.

   - **For all disposable electrodes**: Lightly tug on the connector to ensure that the lead is securely attached. If the electrode comes off, replace it with a new electrode. If the connector comes off, reconnect it.

     WARNING Patient injury risk. To prevent cross-contamination and the spread of infection:
     - Dispose of single-patient use components (for example, electrodes) after use.
     - Regularly clean and disinfect all components that come in contact with patients.
     - Reprocess the device accessories (for example, patient cable, leads, and reusable electrodes) between patients.

     NOTE To maintain the quality of signals during long-term monitoring, replace the electrodes at least every 48 hours. Over longer periods, the electrode gel can dry out and the patient's skin can be irritated by the gel or adhesive. When replacing the electrodes, do not position the new electrodes on exactly the same locations, but a little to the side of the original position.

Maintenance

Clean the equipment

WARNING Keep the ECG module, reusable electrodes, and the patient cable clean. Patient contact with contaminated equipment can spread infection.

CAUTION Never use acetone, ether, freon, petroleum derivatives, or other solvents to clean the ECG module or patient cable. Never immerse the ECG module or the patient cable in liquid. Never autoclave or steam clean the ECG module or the patient cable. Never pour alcohol directly on the ECG module or the patient cable, and never soak any components in alcohol. If any liquid enters the ECG module, remove the ECG module from service, and have it inspected by a qualified service person before using it again.

Clean the ECG module with one of the following approved cleaning wipes or solutions:

- Clorox HP - Hydrogen Peroxide Cleaner Disinfectant Wipes (Clorox Healthcare®)
- Dispatch Hospital Cleaner Disinfectant Towels with Bleach (Clorox Healthcare®)
- CleanCide Wipes (Wexford Labs)
- 70% Isopropyl Alcohol
- 10% Chlorine Bleach

Follow these steps to clean the equipment:

1. Power down the device and disconnect AC power.
2. Dampen a cloth with any of the acceptable cleaning solutions or select one of the approved cleaning wipes, and wipe the exterior of the ECG module.

   WARNING Clean any reusable electrodes you might use between each patient. Follow manufacturer's instructions for cleaning reusable electrodes.

   CAUTION Wring out excess disinfectant from cleaning wipes or towels before using them.

   CAUTION Avoid using cleaning solutions on metal parts, such as USB interface pins and patient connector pins, to prevent corrosion.
3. Dry the module with a clean, soft cloth or paper towel.
4. Clean the cables in the same manner.
5. Before you turn on the ECG module again, wait at least 10 minutes for all traces of liquid to evaporate.

Inspect the equipment

Perform the following inspections daily:

- Check for cracks or breaks in the ECG patient cable, the USB cable, and the ECG module housing.
- Check for bent or missing pins on all cables.
- Check all cable and cord connections; reseat if any connectors are loose.

Store the equipment

When storing the ECG module, cords, and accessories, observe the environmental storage conditions that are identified in the product specifications.

Discard the equipment

Discard the ECG module, cables, and accessories according to local laws.

Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2012/19/EU of the European parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply. For more specific disposal information, see www.welchallyn.com/weee or contact Hillrom Technical Support: hillrom.com/en-us/about-us/locations/.

Troubleshooting

See the *Welch Allyn Connex® Devices Instructions for use* for troubleshooting information.

EMC guidance and manufacturer's declarations

EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with IEC EN 60601-1-2:2007.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document and the *Welch Allyn Connex Devices Instructions for Use*.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The monitor complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the monitor in the presence of high-frequency surgical equipment.
- However, it is good practice to avoid using the monitor in extremely close proximity to other equipment.

Emissions and immunity information

The ECG module is designed for and has been tested as part of a Connex Devices system (Connex Vital Signs Monitor or Connex Integrated Wall System). Therefore, the Emissions and immunity information provided for Connex Devices includes the connected ECG module accessory. For information about electromagnetic compatibility (EMC) of this system, see the Hillrom website:

https://www.hillrom.com/en/knowledge/resources/emc-compliance/#CVSMCIWS

You can order a printed copy of the Emissions and immunity information from Welch Allyn for delivery within 7 calendar days.

Specifications

Physical specifications

Characteristic	Specification
Length	101.6 mm (4.00 in.)
Width	57.15 mm (2.25 in.)
Height	27.94 mm (1.10 in.)
Weight	73.71 g (2.60 oz.)
Protection against the ingress of liquid	IPX0 = No protection against liquid ingress.
Device classification	
EMC Class	Class IIB
IEC Type	Type CF

Environmental specifications

Characteristic	Specification
Operating temperature	50° F to +104° F (10° to 40° C)
Storage temperature	-4° F to +122° F (-20° to +50° C)
Operating humidity	15 to 95% non-condensing
Storage humidity	15 to 95% non-condensing
Operating altitude	-557 to 10,000 ft. (-170 to 3048 m)
Storage altitude	-557 to 50,000 ft. (-170 to 15500 m)

ECG specifications

Characteristic	Specification
Heart rate detection range	20 to 300 beats per minute
Heart rate accuracy	±3 beats per minute or ±3%, whichever is greater
QRS detection amplitude	≥0.3 mV and ≤5.0 mV with QRS width of between 40 ms and 120 ms
Tall T wave rejection	Rejects Tall T waves less than 1.4 mV
Heart rate meter accuracy and response to irregular rhythm	The Heart Rate shall stabilize within 20 seconds and report the following Heart Rates for data sets A.1 to A.4 with accuracy of ±5 BPM: A.1 Ventricular bigeminy 80 BPM A.2 Slow alternating ventricular bigeminy 60 BPM A.3 Rapid alternating ventricular bigeminy 120 BPM A.4 Bidirectional systoles 90 BPM
Response time of heart rate meter to change in heart rate	Increasing from 80 to 120 beats/minute: 10 sec Decreasing from 80 to 40 beats/minute: 10 sec
Time to alarm for tachycardia	Waveform B1 Amplitude – Average time to alarm: • 0.5 mV – 10 seconds • 1.0 mV – 10 seconds • 2.0 mV – 10 seconds Waveform B2 Amplitude – Average time to alarm: • 1.0 mV – 10 seconds • 2.0 mV – 10 seconds • 4.0 mV – 10 seconds
Data storage capacity	24 hours
Pacemaker detection	±2 mV to ±700 mV amplitude; 0.5 ms to 2.0 ms pulse width per EN 60601-2-27: 2011. Rejects pacemaker signals, including double-paced signals, with over/undershoot with the exception of pacemaker signals having an overshoot with a time constant from 4 ms to 100 ms. **NOTE** For leads I, II, III only. The module does not detect or display pacemaker pulses on lead V.
A/D bit resolution	0.5 µV

Characteristic	Specification
Dynamic range	±300 mV (95% gain accuracy)
Sampling rate	250 ±2% samples per second
Mains filter	50 Hz, 60 Hz, off (default = 60 Hz)
Frequency range	0.5 to 70 Hz
Power source	USB (4.5 V to 5.5 V)
Digital data interface	Serial (USB – Full Speed)
Monitoring period	Continuous
ECG channels	Supports 3-lead or 5-lead
Sweep speed	25 mm/sec, 50 mm/sec
Resolution	14 bit ECG data, 30 mV peak-to-peak dynamic range minimum
Lead-off detection	3-lead or 5-lead
Applied currents	Lead connection failures are detected by a bias current with respect to the reference electrode.
User-adjustable parameters	See Alarms

ECG cable specifications

Characteristic	Specification
Connector at ECG module	80 in. ±1 shielded cable to a 24 in. ±1 lead fan-out to electrode connection
ECG cables	3-lead or 5-lead to snap connection
Patient cables	Conforms to ANSI/AAMI EC53

Impedance respiration specifications

Characteristic	Specification
Impedance Respiration accuracy	±2 breaths per minute or ±2%, whichever is greater
Range	5 to 100 breaths per minute
Breath detection range	0.4 ohms to 3.0 ohms

Characteristic	Specification
Respiration lead source	Lead II (right arm and left leg) **NOTE** Respiration can only be acquired from Lead II.
Respiration, leads-off sensing and active noise suppression (applied currents)	Respiration – Excitation signal characteristics Less than 25 uA RMS at 31 kHz pseudo sine wave Lead off – DC current of 50nA max for RA ,LA, LL, V; 200nA max for RL Noise suppression – DC current of 200nA max for RL

Software and alarm specifications

Characteristic	Specification
Ventricular tachycardia threshold default	120 beats per minute ±3 beats per minute for 6 consecutive beats
Variable ventricular tachycardia settings	100 beats per minute to 150 beats per minute ±3 beats per minute for 6 consecutive beats
Asystole threshold default	No detectable beat for ≥4 seconds
Ventricular fibrillation threshold default	A fibrillatory waveform persisting for ≥4 seconds
Configurable mains filter	ON or OFF; 50 Hz or 60 Hz
Data stream bytes output	Maximum latency <100 ms
Heart rate averaging method per IEC 60601-2-27:2011 Clause 201.7.9.2.9.101	Number of consecutively detected beats: >10: Heart rate = 60/(average of last 10 detected consecutive R-R intervals) >2 and <10 : Heart rate = 60/(average of the detected consecutive R-R intervals)
Response to change in Heart rate per IEC 60601-2- 27:2011 Clause 201.7.9.2.9.101	Increasing from 80 to 120 beats/minute: 6.0 sec Decreasing from 80 to 40 beats/minute: 16.0 sec

Protection against defibrillation

Defibrillation protection per EN60601-2-27:2011. ECG device will resume according to the table below.

Parameter	Initial report after defibrillation	Maximum time to recover	Note
HR value	Acquiring	3 sec +5 beats	Depends on patient heart rate
ECG waveform	Waveform	≤5 sec	
Respiration value	Acquiring	3 sec +5 breaths	Depends on patient respiration rate
Pacer detect	Pacer marker in waveform	≤5 sec	
Arrhythmia	Acquiring or Cannot analyze	5 sec +5 beats	Depends on patient heart rate

Protection against electrosurgical

Electrosurgical protection per EN60601-2-27:2011. ECG device will resume as per the table below.

Parameter	Initial report after defibrillation	Maximum time to recover	Note
HR value	Acquiring	10 sec +5 beats	Depends on patient heart rate
ECG waveform	Waveform	≤10 sec	
Respiration value	Acquiring	10 sec +5 breaths	Depends on patient respiration rate
Pacer detect	Pacer marker in waveform	≤10 sec	
Arrhythmia	Acquiring or Cannot analyze	10 sec +5 beats	Depends on patient heart rate

Device classification

ECG device will operate per table below after startup and after changes to parameter configurations (e.g., filter on/off) or lead off recovery.

Parameter	Initial report after defibrillation	Maximum time to recover	Note
HR value	Acquiring	10 sec +5 beats	Depends on patient heart rate
ECG waveform	Waveform	≤3 sec	
Respiration value	Acquiring	10 sec +5 breaths	Depends on patient respiration rate
Pacer detect	Pacer marker in waveform	≤3 sec	
Arrhythmia	Acquiring or Cannot analyze	10 sec +5 beats	Depends on patient heart rate

Default settings

Characteristic	Specification
Lead color code	AHA
Lead for view	II
Sweep speed	25 mm/second
Gain	10 mm/mV
Arrhythmia detection	Enabled
Impedance Respiration	Disabled
Print on V-Tach, V-Fib, and Asystole alarms	Enabled
Pacer	Disabled

Regulatory compliance

The ECG module complies with the following standards[1]:

IEC 60601-1

IEC 60601-1-2

IEC 60601-1-6

IEC 60601-2-27[2]

ISO 10993

IEC 62304

IEC 62366

[1] Standard is essentially the IEC 60601-1 General standard plus the listed country's National Deviations(e.g., AS/NZ, CAN/CSA, EN Harmonized version, etc.).

[2] Alarms might display and sound during an Electrosurgery Interference event.

Appendix

Approved accessories

ECG

Part Number	Description
6000-CBL3I	Patient cable 3L IEC
6000-CBL3A	Patient cable 3L AHA
6000-CBL5I	Patient cable 5L IEC
6000-CBL5A	Patient cable 5L AHA
6000-ECG3I	Module + USB + Patient cable 3L IEC
6000-ECG3A	Module + USB + Patient cable 3L AHA
6000-ECG5I	Module + USB + Patient cable 5L IEC
6000-ECG5A	Module + USB + Patient cable 5L AHA
6200-11	Electrode pads (30 pads/pack, 20 packs/box)
420507	Connex ECG Module CD, Instructions for Use, Quick Reference, Multi-language

Limited warranty

Welch Allyn, Inc., warrants that the ECG/Impedance Respiration module (the Product) meets the labeled specifications of the Product and will be free from defects in materials and workmanship that occur within 1 year after the date of purchase, except that accessories used with the Product are warranted for 90 days after the date of purchase. Such accessories include cables and electrodes.

The date of purchase is the date specified in our records, if you purchased the Product directly from us. If you purchased from a distributor, the date of purchase is the date specified on your invoice.

This warranty does not cover damage caused by: 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Welch Allyn, and 4) accidents.

If a product or accessory covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period described above, Welch Allyn will, at its discretion, replace the defective Product or accessory free of charge with a like-new Product.

You must obtain a return authorization from Welch Allyn to return your Product before you send it to Welch Allyn's designated service center for repair. Contact Welch Allyn Technical Support.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILTY AND FITNESS FOR A PARTICULAR PURPOSE. WELCH ALLYN'S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. WELCH ALLYN IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY.