EXHIBIT L – User Manual Addendum for Radio

FCC ID# PGU3021-100

UPDATE

Propaq CS® Directions For Use

Update for Software Version 3.4X

Keep this update in the back pocket of your manual.

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About this Update

This Update describes the operation of the Propaq® CS monitor (software version 3.40) with the Acuity® FlexNet™ network. It describes both the Acuity hardwired and wireless communication options for the Propaq CS monitor.

Use the Acuity System in compliance with the instructions in this Update, the *Propaq CS Directions for Use*, the *Acuity System Reference Guide*, and accepted hospital and clinical protocols.

General Warnings and Cautions

Warning

When connecting the Acuity hardwire connection, connect the Propaq CS monitor to an Acuity system only. Connecting to other networks could damage the monitor or injure the patient. If in doubt about the network jacks or devices, consult your facility's Biomedical Engineering Department.

Make sure the Acuity network cable is not damaged. If the wireless connection is not an option or not available, the Acuity network cable is the sole link between the Propaq CS monitor and the Acuity Central Station.

When considering a treatment protocol that involves wireless communication of patient data, be sure to recognize some limitations inherent in wireless communications. When the Propaq CS monitor is not connected to the network by wireless (or hardwired) connection:
- There are no patient alarms or alerts at the Acuity Central Station.
- Acuity does not perform arrhythmia and ST analysis on the patient data and does not generate related alarms.

If wireless communication is no longer available or is not functioning properly, consider using the hardwire connection to Acuity.

If you don't set alarm limits, the Acuity system uses preset settings (for arrhythmia test limits), and the powerup default settings for the Propaq CS monitor.

The radio in this monitor has been authorized by the FCC for mobile use only. Mobile use as defined by the FCC is for operation 20 cm or more away from a person's head or torso. The distance does not apply to transient exposure due to incidental passage closer than the maximum permissible exposure (MPE) limit.

Caution

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g., EN 60950 for data processing equipment and EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 601-1-1. Anyone connecting additional equipment to the signal input or output connectors is configuring a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 601-1-1. If in doubt, consult your Biomedical Engineering Department.

Note

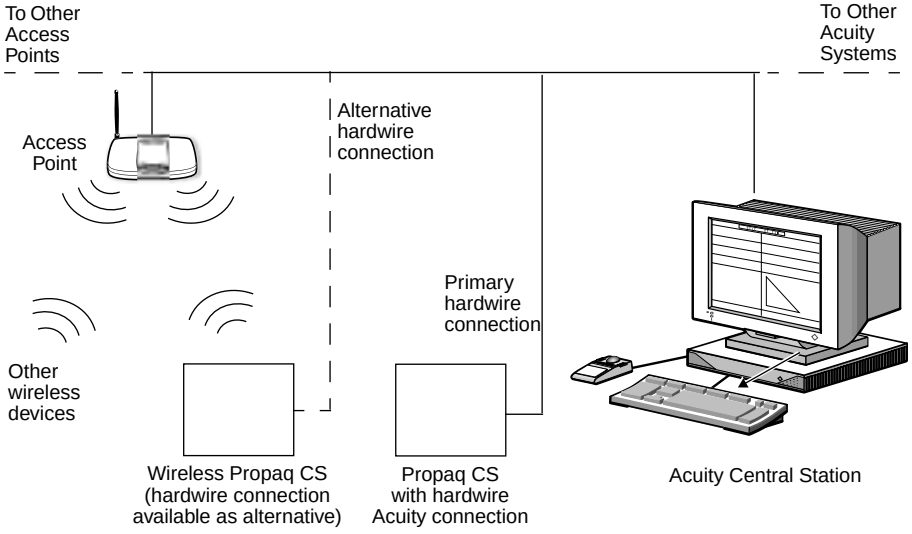
WHEN USED IN CANADA:
To prevent radio interference to the licensed service, this device is intended to be operated indoors and away from windows to provide maximum shielding. Equipment (or its transmit antenna) that is installed outdoors is subject to licensing.

Pour empêcher que cet appareil cause du brouillage au service faisant l'objet d'une licence, il doit être utilisé à l'intérieur et devrait être placé loin des fenêtres afin de fournir un écran de blindage maximal. Si le matériel (ou son antenne d'émission) est installé à l'extérieur, il doit faire l'objet d'une licence.

Understanding the Propaq CS, Acuity, and the FlexNet™ Network

The Propaq CS monitor can communicate with an Acuity® Central Station as part of Welch Allyn's FlexNet network. FlexNet allows multiple devices to communicate through hardwired Ethernet networks and Wireless Local Area Networks (WLANs). The Acuity Central Station provides central patient monitoring for monitoring devices connected to the network.

As shown below, the Propaq CS can communicate through a hardwire Acuity connection. In addition, the Propaq CS can also be equipped with the Wireless option which allows two-way wireless communication with an Acuity Central Station through an access point in the FlexNet network. The access point is a digital radio transceiver that connects to the FlexNet network.



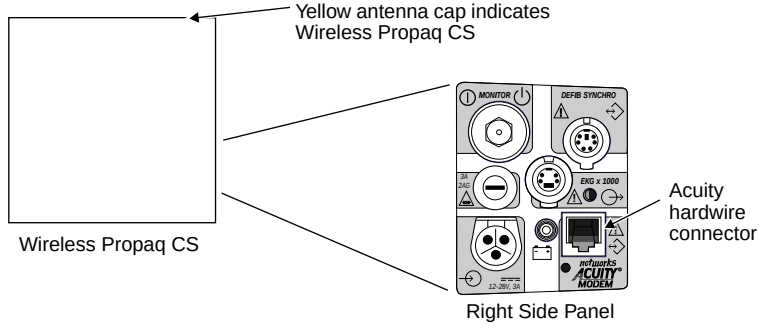
FlexNet Network

While connected to the network, the Propaq CS sends patient data to Acuity. Acuity continuously analyzes the data and provides appropriate alarm or alert messages at the Central Station and other network devices such as a hallway message panel or the Propaq CS itself. Acuity also stores the patient data for viewing or report printing.

If the Wireless Propaq CS is moved out of range or loses communication with the FlexNet network and Acuity, it continues to monitor the patient and display patient data. While not communicating with Acuity, the Propaq CS continues to generate local patient alarms or alert messages. Acuity does not perform waveform analysis or generate arrhythmia messages while the Propaq CS is not communicating with Acuity. When the Wireless Propaq CS is returned to within range of the FlexNet network, it automatically reconnects to Acuity.

A Propaq CS with the Acuity hardwire connection can be identified by the Acuity connector on the right side panel.

A Wireless Propaq CS can be identified by the blue antenna cap on the top right corner of the monitor in front of the carrying handle. Every Wireless Propaq CS also has the Acuity hardwire connection.

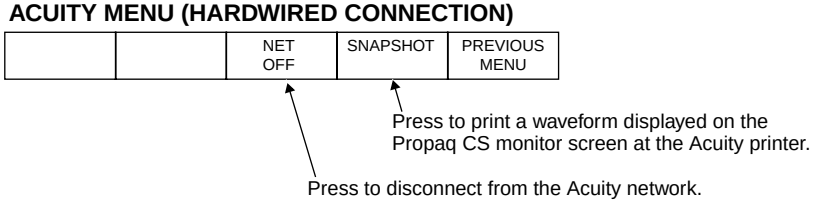


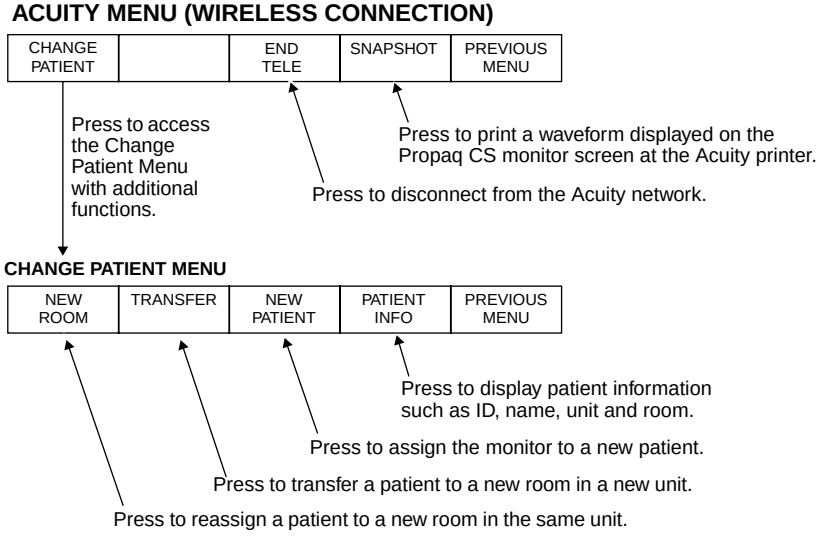
If a Wireless Propaq CS monitor is communicating with the network via the wireless interface and then the Acuity hardwire cable is used to connect the bedside Acuity network jack and the monitor, the monitor disconnects from the wireless connection and communicates through the hardwire connection. There may be a short interruption in the display of patient waveforms at Acuity while this change occurs.

The Acuity Menu

The Acuity Menu on the Propaq CS allows you to control some of the interaction with the Acuity network. The Acuity Menu is only accessible while the monitor is connected to the Acuity network.

The Acuity Menu for the Wireless Propaq CS provides additional functions that allow you to manage the patient assignment and patient location from the monitor. These functions are described later in this document.





Hardwired Connection to Acuity

Connect the Monitor to the Acuity System

1. If the Propaq CS monitor has already been connected to the patient, save the patient's Trends and Alarm Limit settings by keeping the monitor turned on.

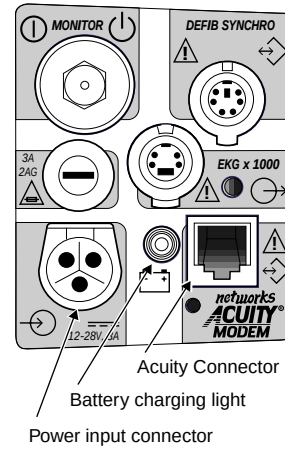
   The monitor transmits up to five hours of trend information when you connect it to the Acuity network.

   If the monitor has not been connected to the patient, clear any prior patient's trends and alarm limit settings by turning off the monitor, then turning it on after a few seconds.

2. If the monitor is not already connected to the patient, attach leads and sensors to the patient as described in the *Propaq CS Directions For Use*.

3. Plug in the Acuity network cable to the Acuity network jack on the monitor side panel as shown. Plug in the other end of the cable to the bedside Acuity network jack.

4. Connect the ac power adapter to the monitor and the wall outlet to charge the battery. Check to see that the green battery charging light on the monitor's right side panel is on.



5. When the monitor completes the connection to Acuity, it displays the message ON NETWORK (or alternating messages ON NETWORK and SERIAL if the monitor has wireless capability). Confirm the patient identification at the bedside or enter the patient information at the Acuity Central Station using the Patient ID Setup Window.

6. If alarm limits have not been set, do so at the monitor or at the Acuity Central Station using the Alarms Setup Window.

Note

When a Propaq CS monitor in Adult or Pediatric Mode is connected to an Acuity System, the audible alarms at the bedside Propaq CS monitor can be delayed up to 4 minutes and 15 seconds. The delay time is selected in Acuity software at the time of Acuity installation. Visual alarm indications are not delayed.

Disconnect the Hardwired Monitor from the Acuity System

1. To permanently disconnect the Propaq CS monitor from the Acuity network, press the **NET OFF** key on the upper left corner of the monitor display. (From the Main Menu you can also press **SETUP, ACUITY**, **NET OFF**.)

2. Within 15 seconds, disconnect the Acuity network cable from the Propaq CS monitor side panel and the bedside jack. If the patient will no longer be monitored with this monitor, turn off the monitor to erase trend information.

   If you want to temporarily disconnect the Propaq CS monitor from the Acuity network and reconnect the same patient to the Acuity network later, see the *Acuity System Reference Guide*.

Note

If the Propaq CS has the wireless option, be aware that after you disconnect the hardwire connection and disconnect the Acuity network cable, the Wireless Propaq CS will attempt to establish a wireless connection to Acuity as long as the power is on.

Switch from Hardwired to Wireless Monitoring

Follow these steps to switch a Wireless Propaq CS monitor from a hardwired Acuity connection to a wireless Acuity connection.

1. Press the **NET OFF** key on the upper left corner of the monitor display to disconnect from Acuity. (From the Main Menu you can also press **SETUP, ACUITY**, **END TELE**.)

2. Within 15 seconds unplug the Acuity network cable from the Wireless Propaq CS Acuity connector and the Acuity bedside network jack.

   The Wireless Propaq CS automatically seeks to establish a wireless connection to the Acuity network.

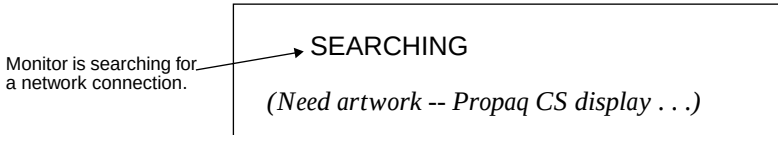
3. After the network connection is established, select the Acuity Unit, patient, and room from the Wireless Propaq CS as described on page 16.

Wireless Connection to Acuity

Connect a New Patient

1. Make sure the Acuity network cable is not plugged into the Acuity connector and an Acuity bedside network jack. Turn on power to the Wireless Propaq CS. The monitor displays the powerup screen for about 10 seconds, then displays the Main Menu. The monitor is in the powerup patient mode with the associated settings.

2. Confirm that the Wireless Propaq CS displays the flashing message SEARCHING in the upper left corner of the display.



Within a short time the monitor displays the flashing message CONNECTING. This indicates the monitor has associated with an access point but is not fully connected to the Acuity network.

3. Confirm that within one minute the monitor displays these alternating messages:

   ON NETWORK and WIRELESS

   This indicates the Wireless Propaq CS is connected to the Acuity network.

4. After the network connection is established, the monitor may prompt you to select an Acuity Unit (if your facility has more than one Acuity unit). Scroll up or down to highlight the desired Acuity Unit, then press **Select**.

5. The Wireless Propaq CS displays a list of possible patients. If your patient has been pre-admitted to the selected Acuity unit, they will be included in the list.

- If your patient is NOT in the list, highlight Select Patient at Acuity and press **Select.**

  The patient name will need to be entered later at the Acuity Central Station.

Warning

If you do not select the patient name at the Wireless Propaq CS at this time, do not adjust any alarm limits until **after** the patient name and ID are confirmed at Acuity. When the patient name and ID are confirmed at Acuity, Acuity downloads the default settings and patient alarm limits for that Acuity unit to the Wireless Propaq CS, thereby overriding any previous settings and alarm limits.

- If your patient is in the list, scroll to highlight your patient's name, then press **Select.**

6. Within a few seconds the Wireless Propaq CS displays a list of unassigned rooms.

- If you want to assign the patient to a room, highlight the room and press **Select.**
- If you do not want to assign a room at this time, highlight Select Room at Acuity and press **Select.**

  The patient room will need to be entered later at the Wireless Propaq CS (see page 17) or at Acuity (see the *Acuity System Reference Guide* or *Acuity Directions For Use*).

7. Customize alarm limits for your patient if needed. Refer to the *Propaq CS Directions For Use.*

Monitor a Patient Out of Range of Acuity

While out of range of Acuity, the Wireless Propaq CS continues to monitor the patient and provide local alarms or alerts at the Propaq CS as needed.

When the patient with the Wireless Propaq CS goes out of range of Acuity, do the following:

1. A DROPOUT equipment alert occurs at the Acuity Central Station. Acknowledge the alert at Acuity.

2. An equipment alert occurs at the Wireless Propaq CS with this message:

   NETWORK FAULT
   CHECK ACUITY/NETWORK CONNECTION

   Press a key on the Propaq CS to acknowledge the alert and silence the alert tones (if tones are enabled).

When the patient with the Wireless Propaq CS returns within range of Acuity, the Propaq CS automatically reconnects to Acuity. No clinician intervention is required.

Stop Monitoring a Patient

If you want to discontinue monitoring the patient, follow these steps.

1. Press the **NET OFF** key on the upper left corner of the monitor display. (From the Main Menu you can also press **SETUP, ACUITY**, **END TELE**.)

2. Disconnect the leads and sensors from the patient and turn off the power to the monitor.

   If you do not turn off power to the monitor within about 30 seconds, the Wireless Propaq CS will automatically try to reconnect to the network.

   If you do not use NET OFF or END TELE to disconnect from the network as described above, the Acuity Central Station generates a DROPOUT equipment alert at Acuity.

   If you want to monitor this same patient at a later time, you will need to re-select the patient name from Wireless Propaq CS or confirm the patient ID at Acuity.

Reconnect a Recently Monitored Patient

1. Turn on power to the Wireless Propaq CS and confirm that the monitor displays the powerup screen.

2. The Wireless Propaq CS will then present a series of menus and messages requesting you to provide information about the connection and patient. The actual screens presented depend on how long the patient has been disconnected.

   Provide the information as requested. This may include:

   - Select an Acuity unit.
   - Select a patient from the patient list.
   - Select a patient room from the room list.

     If you do not select the patient name or room while connecting the patient, you will need to do that later at the Acuity Central Station. See the *Acuity System Reference Guide* or *Acuity Directions For Use* for more information.

Reassign a Monitored Patient to a New Room in the Same Unit

If a patient is being monitored and you want to assign them to a new room in the same unit, follow these steps.

1. From the Main Menu, press **SETUP, ACUITY, CHANGE PATIENT, NEW ROOM**.

   Within a few seconds the Wireless Propaq CS displays a list of all available rooms, including the patient's current room.

   - If you decide not to change the patient's current room assignment, press **Select** (the patient's current room is the default selection in the list).
   - To assign the patient to a new room, scroll up or down to highlight the room and press **Select**.
   - If you want to cancel the patient's current room assignment, but do not want to assign a new room at this time, you can highlight Select Room at Acuity and press **Select**. You can then assign the room later from the Acuity Central Station, or you can repeat this procedure and assign a new room from the Wireless Propaq CS.

Transfer a Monitored Patient to a New Room in a Different Unit

If a patient is being monitored and you want to assign them to a new room in a different unit, follow these steps.

1. From the Main Menu, press **SETUP, ACUITY, CHANGE PATIENT, TRANSFER**. Within a few seconds the Wireless Propaq CS displays a list of units.

2. Scroll up or down to highlight the new unit, then press **Select**.

   The patient is not monitored at Acuity during the short time required by Acuity to process the transfer to the new unit (typically less than one minute). However, the patient continues to be monitored by the Wireless Propaq CS.

   (If the selected unit is currently not available, the Wireless Propaq CS displays an appropriate message; press a key to acknowledge the message and cancel the transfer.)

3. After the patient is assigned to the new unit, the Wireless Propaq CS displays a list of unassigned rooms. (The patient's previous unit and room assignment is cancelled.)

   - To assign the patient to a new room, highlight the room and press **Select**.
   - If you decide not to assign the patient to a new room at this time, you can highlight Select Room at Acuity and press **Select**. You can then assign the room later from the Acuity Central Station, or you can assign a new room from the Wireless Propaq CS later using the procedure on page 17.

Reassign the Wireless Propaq CS to a New Patient

If you want to discontinue monitoring a patient and connect the Wireless Propaq CS to a new patient, follow these steps.

1. From the Main Menu, press **SETUP, ACUITY, CHANGE PATIENT, NEW PATIENT.**

   The monitor then presents a series of menus and messages requesting you to provide information about the connection and patient. The actual screens presented depend on how the Acuity System is configured.

   Provide the information as requested. This may include:

   - Select an Acuity unit.
   - Select a patient from the patient list. (After you select a new patient, all monitor operating settings are reset to the Acuity System default powerup settings.)
   - Select a patient room from the room list.

     If you do not select the patient name or room while connecting the patient, you will need to do that later at the Acuity Central Station. See the *Acuity System Reference Guide* or *Acuity Directions For Use* for more information.

Switch from Wireless to Hardwired Monitoring

1. Plug the Acuity network cable into the Wireless Propaq CS Acuity connector and an Acuity bedside network jack.

   The Wireless Propaq CS will automatically switch to a hardwired Acuity network connection. No equipment alerts are generated.

Equipment Alert Messages

The following equipment alerts can occur when operating the Propaq CS monitor with the Acuity network.

CHECK ACUITY/SERIAL CONNECTION. The Propaq CS detects a problem in the hardwired (serial) communication with Acuity. Check the Acuity network cable to be sure it is plugged into the side panel and the bedside Acuity jack. If the cable is damaged, replace the cable. If the cable appears undamaged and the Acuity system is operating normally, contact biomedical engineering for assistance.

CHECK ACUITY/NETWORK CONNECTION. The Wireless Propaq CS detects a problem with the wireless communication with Acuity. The monitor might be out of range of the network, or there might be a problem involving the monitor radio card, the access point, or the Acuity system. If the problem persists, contact biomedical engineering for assistance.

Specifications

Wireless Propaq CS Radio Specifications

Characteristic	Specification
FlexNet Network	2.4 GHz Wireless Local Area Network (WLAN) and 10/100 Base-T Ethernet network
Frequency[1]	2.402 to 2.480 GHz
Modulation	GFSK, Frequency Hopping Spread Spectrum (FHSS)
Output Power	112 mW (maximum)
IEEE 802.11 compliant	Yes
Wireless Propaq CS monitors per Access Point	7 (max.)

1. When used within certain countries, authorization for use is restricted as follows:
   - France: The equipment is internally restricted to the 2.448-2.482 GHz frequency range.
   - Spain: The equipment is internally restricted to the 2.447-2.473 GHz frequency range.
   - Japan: The equipment is internally restricted to the 2.473-2.495 GHz frequency range.
   - Italy: Operation requires a user license.

Note: The frequency ranges specified above are subject to geographic-specific regulatory authorities.