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Intended Use

The Propaq LT Series (802LT0N and 802LTRN) monitors are portable devices intended to be used by clinicians and medically qualified personnel for single or multiparameter vital-signs monitoring of ambulatory and nonambulatory neonate, pediatric and adult patients. These devices are indicated for ECG, noninvasive blood pressure (NIBP), respiration and $\rm SpO_2$. The most likely locations for patients to be monitored by these devices are hospital general medical-surgical, telemetry, and intermediate care floors, hospital emergency departments, transport, emergency medical services, and other healthcare applications.

The monitors can be used as standalone devices or as devices networked to an Acuity Central Station (referred to in this manual as 'Acuity') through wireless communication over a Welch Allyn FlexNet network.

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

Even though this manual describes some monitoring techniques, the monitor is intended for use only by trained and experienced clinicians who know how to measure and interpret vital signs.

Symbols

Table 1. Directions for Use



WARNING Indicates conditions that could lead to illness, injury, or death.



Caution In this manual, indicates conditions that could damage equipment or other property.



Caution On the product, means "Consult the accompanying documentation."

Table 2. Control Buttons



Power - Turn the monitor power on or off.



Monitor

Down - Move the cursor down to the next display



Action - Act based on what is highlighted. (See "Using the Action Button" on page 32.)



Silence/Reset - Silence the current alarm tone for 90 seconds or reset a silenced alarm tone.



Left - Move the cursor left to the next display item; decrease the parameter value.



Display - Cycle to the next configured display format, or cancel the current control, setup, or



Right - Move the cursor right to the next display item; increase the parameter value.



Snapshot - Record a 21-second period of numeric and waveform data.



Up - Move the cursor up to the next display item.



Cradle

Start/Stop NIBP - Start or stop an NIBP measurement.

Monitor Release - Press and then hold while removing the monitor from the cradle.

Table 3. Status Indicators

Monitor



(green) Monitoring normally (no active alarms or alerts). Connection to Acuity is confirmed and patient identification is confirmed. (Wireless only, Acuity enabled.)



(green flashing) Monitoring normally (no active alarms or alerts). (Standalone only.) Patient confirmed, and monitor then intentionally disconnected. (Wireless only, Acuity enabled.)



(yellow) At least one alarm is disabled.

Monitor disconnected, connecting or connected; patient not confirmed. (Wireless only, Acuity enabled.)



(yellow flashing) Equipment alert. Acuity message windows. (Wireless only, Acuity enabled.)



(red flashing) Patient alarm.

Table 3. Status Indicators (continued)

Upper and lower alar

Upper and lower alarm limits for this parameter are on.

The upper alarm limit for this parameter is on and the lower is off.

The upper alarm limit for this parameter is off and the lower is on.

Upper and lower alarm limits for this parameter are off.

A snapshot exists for this period.

The snapshot for this period has been replaced with a more recent snapshot.

(green) The battery is fully charged.
The battery is partially full.

The battery is partially full and is charging.

(yellow) The battery is low.

The battery is low and is charging.

(red) The battery is near failure; the monitor will shut down soon. If this indicator appears while the monitor is in the cradle, the battery cannot be charged and must be replaced.

The battery is near failure and is charging. The monitor will shut down if removed from the cradle. The monitor is communicating wirelessly with the network and with Acuity. (**Wireless only, Acuity**

The monitor is not communicating with the wireless network. (Wireless only, Acuity enabled.)

(Flashing) The monitor is communicating with the network but is not communicating with Acuity. (Wireless only, Acuity enabled.)

The monitor is communicating by USB cable with a PC.

Cradle

(green) Cradle is powered.

(green) Monitor battery is charging.

NOTE: When the battery is fully charged, this indicator is not lit.

(yellow) Cradle fault or battery fault, or the monitor is not properly seated in the cradle.

Table 4. Labels

Monitor



Proceed with caution. If in doubt, refer to the accompanying documentation.



Enclosure protection: Drip-proof. Class IPX1 per EN60529:1991.



The monitor or accessory meets all essential requirements of the European Medical Device Directive



The monitor is certified by the Canadian Standards Association International to comply with applicable US and Canadian medical safety standards.



The monitor or accessory meets all essential requirements of the European Medical Device Directive 93/42/EEC for a Class I product.



Type CF patient connections, isolated for direct cardiac application and protected against defibrillation.



Australian registered importer.

93/42/EEC for a Class II-b product.



Hazard Class 9, IATA/ICAO (International Air Transport Association/International Civil Aviation Organization).



High voltage. Do not touch during defibrillation.



Direct current.



Recycle the battery separately from other disposables.



Li ++ 7.4v === Battery replacement specification.



Electromagnetic interference might occur in the vicinity of this monitor. (**Wireless only, Acuity enabled**; see "EMC Compliance" on page 179.)

Power in (DC).



Recycle the monitor, cradle, and battery separately from other disposables. (See "Recycling Monitor Components" on page 162.)



Lithium-ion battery.





Product Packaging



Fuse replacement specification.



→ 12-28V=== 3A

USB cable connector.



For indoor use only.



Input power (DC) pin pattern.











Temperature limits.



Altitude limits.



Rain protection required.



Contents are fragile.



Stacking limit.



Recycle the packaging material.

Safety

The monitor is safe for patients and clinicians when used in accordance with the instructions and with the warning and caution statements presented in this manual.

All personnel must read and understand all warning and caution statements presented in this manual before using the monitor.

- 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 equipment damage or loss of patient data.

General Warnings

These statements apply to all aspects of patient monitoring. Statements which apply specifically to one aspect of monitoring, such as NIBP or SpO_2 monitoring, are presented in the corresponding sections of the manual.



WARNING Many environmental variables, including patient physiology and clinical application, can affect the accuracy and performance of the monitor. The clinician must verify all vital-signs information prior to patient intervention.

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. Make sure the monitor has settings that are appropriate before monitoring the patient.

WARNING Make sure Acuity patients, and especially those prone to arrhythmias, are kept under close surveillance. While monitoring patients with Acuity, the clinician must review all clinical data *before* implementing therapy. As with all computerized arrhythmia analysis systems, Acuity cannot replace skilled care and proper surveillance by a clinician.

WARNING It is possible for Acuity alarms, alerts, or other events to go unnoticed if clinical personnel are not present at Acuity or if interruptions occur in power or system operations. To help reduce this possible occurrence, Acuity must be installed with redundant power supplies and redundant means of operator surveillance, such as secondary Acuity Central Stations and hallway message panels.

WARNING The monitor might not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.

WARNING Use of respiration monitoring by impedance pneumography can affect the operation of some pacemakers. If pacemaker operation is affected, turn off respiration pneumography. (See Figure 61 on page 61.)

WARNING Do not connect more than one patient to a monitor.

WARNING Do not connect more than one monitor to a patient.



WARNING During defibrillation, keep discharge paddles away from the monitor ECG lead wires, electrodes, any other monitor sensors, and other conductive parts in contact with the patient.

WARNING Do not operate this product in the presence of flammable anaesthetics or other flammable substances in combination with air or oxygen-enriched environments. Failure to observe this warning can result in an explosion.

WARNING Do not use the monitor in a Magnetic Resonance Imaging (MRI) suite or a hyperbaric chamber. Such use can cause fire or explosion resulting in patient injury and monitor damage.

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

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 Pacemaker signals can differ from one pacemaker to the next. The Association for Advancement of Medical Instrumentation (AAMI) cautions that "in some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. All pacemaker patients should be kept under close or constant observation." See "Pacer pulse rejection" on page 165 for disclosure of the pacemaker pulse rejection capability of this instrument.

WARNING Use only accessories supplied by Welch Allyn or recommended in the Welch Allyn *Products and Accessories* guide (810-0409-XX). Use of any other accessories can result in inaccurate patient data and damage to the equipment. Always use accessories according to facility standards and the manufacturer's recommendations. Always refer to the manufacturer's instructions.

WARNING 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 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 properly connect the electrosurgery return circuit. Improper circuit connection can cause current to return through monitor electrodes and probes, creating a burn hazard for patients.

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

WARNING Carefully route and secure patient cabling, using the supplied garment clips. Improperly routed and secured cabling can cause the patient to become entangled in the cables, creating a strangulation hazard.

WARNING When the patient is wearing the monitor or being transported by stretcher with the monitor connected, always take care to position the monitor carrying straps on the patient. Be certain that the straps do not and cannot cross the neck or throat and cause choking, and the straps do not restrict movement of the patient's arms or legs.

WARNING Never use a monitor that is not working properly. If the monitor is not working properly, patient waveforms might be inaccurate or might not be displayed.

WARNING If the monitor is damaged, or if you see any indication that the monitor is not operating properly, disconnect it from the patient. Do not return it to service until it has been inspected and, if necessary, repaired by qualified service personnel.

General Cautions



Caution Do not autoclave the monitor.

Caution Autoclave accessories only if the manufacturer's instructions clearly direct you to do so. Many accessories can be damaged by autoclaving.

Controls, Indicators, and Connectors

Figure 1. Controls

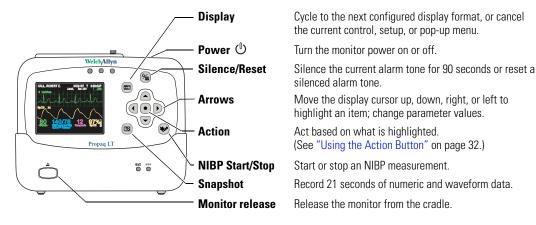


Figure 2. Indicators: Monitor

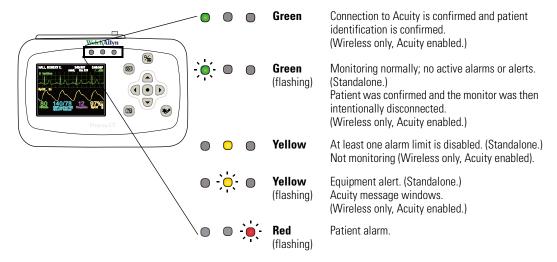


Figure 3. Indicators: Cradle

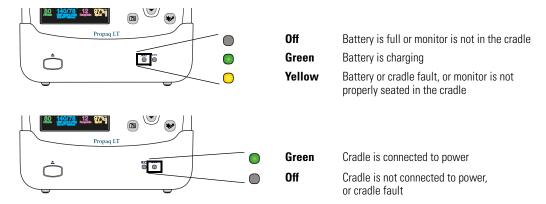


Figure 4. Connectors: Monitor

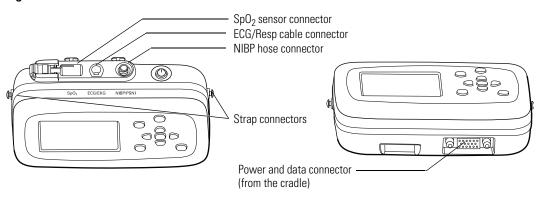
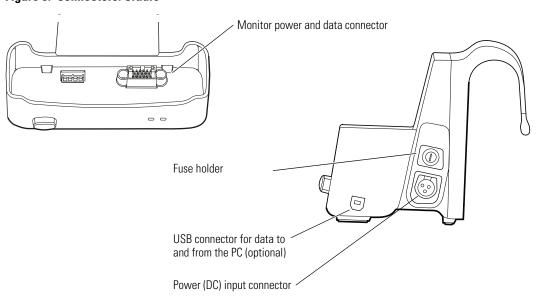


Figure 5. Connectors: Cradle



Features and Functions

- Monitoring of neonate, pediatric and adult patients
- Display of ECG, SpO₂, and Resp waveform traces
- Accurate reading of NIBP in the presence of motion artifact, using Welch Allyn's patented Smartcuf motion-tolerant technology (available in 2006)
- SpO₂ monitoring with advanced technology for accuracy under conditions of low perfusion and in the presence of motion artifact
- Configurable adjustments to alarm limits with ParamSet technology
- Standalone operation with local patient alarms and equipment alerts
- Optional two-way wireless communication within a Welch Allyn FlexNet network, providing monitoring and remote control at an Acuity Central Station
- Color LCD for display of numerics and waveform data
- Configurable display formats and monitoring capabilities
- Internal antenna
- Rechargeable lithium-ion battery
- Weight of approximately 2 pounds (0.9 kg)
- Durability
- Tolerance of brief exposure to water
- HIPAA support
- Error detection

Models

The monitor is available in a standalone model (802LT0N) and a wireless model (802LTRN).

Table 5. Model Descriptions

| Feature | Model 802LT0N | Model 802LTRN |
|------------------------------------------------------------------------------------------------------------------|------------------|------------------|
| 3-lead and 5-lead ECG | Х | Х |
| Respiration rate (Resp) | Х | Х |
| SpO_2 | Х | Х |
| Noninvasive blood pressure (NIBP) | Х | Х |
| Radio for FlexNet wireless communication with Acuity | | Х |
| Cradle to recharge the monitor battery | Х | Х |
| USB | Option | Option |
| Upload patient data from the monitor to a PC and download custom monitor configurations from a PC to the monitor | Option | Option |

Accessories

The following accessories are available for use with the monitor and the cradle:

- Large Color Display Interface and cables
- IV pole mount
- Propag LT Monitor PC Utility software (CD)
- Propag LT Monitor Service Manual (CD)
- Propag LT Monitor Directions for Use (CD)
- Patient carry strap
- Patient wearable strap
- Transport stretcher strap
- Connector panel plugs
- SpO₂ cables and sensors
- 3-lead and 5-lead ECG cables and cable extensions
- ECG electrodes
- NIBP hoses and cuffs
- Battery pack
- AC power adapter



WARNING Use only accessories supplied by Welch Allyn or recommended in the Welch Allyn *Products and Accessories* guide.

WARNING Always use accessories according to your facility's standards and the manufacturer's recommendations.

WARNING Always refer to the manufacturer's directions for use.

For ordering information, see Welch Allyn Products and Accessories (810-0409-XX).

USB Option

The monitor can be purchased with the optional USB data transfer capability. This option is required for the following:

- Downloading custom configuration files from a PC to the monitor.
- Uploading patient vital signs from the monitor to a PC (for printing).

HIPAA Considerations

Each medical facility is responsible for creating and enforcing policies and procedures to guarantee compliance with the regulations defined in 45 CFR 160-164 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

The Propaq LT Monitor, the Large Color Display Interface, the Propaq LT Monitor Configuration Utility, and the Propaq LT Monitor AutoPrint Utility incorporate security features that support your implementation of the HIPAA requirements for ensuring that patient information is kept private and confidential.

Monitor

- Clinicians can lock the monitor display to prevent the display of patient vital signs. For
 patient protection when the monitor display is locked, the display is restored instantly
 in the event of a button press (unless button-pad lock-out is enabled), an alarm or an
 alert.
- Clinicians can lock the monitor buttons to prevent any unauthorized access to the monitor controls. To protect the patient when the buttons are locked, access to the buttons is restored instantly in the event of an alarm or an alert.
- All patient data transmitted by radio from the monitor is fully encrypted. This data can
 be decrypted only by a Welch Allyn Acuity Central Station residing on the local Welch
 Allyn FlexNet network. Transmitted patient data is sent via the 802.11
 spread-spectrum, frequency-hopping protocol, using the Welch Allyn proprietary PSI
 communications protocol.

Configuration Utility

The configuration utility never contains patient data.

AutoPrint Utility

- All patient data is stored in a Welch Allyn proprietary data format which is readable only by machine.
- All patient data is deleted from the PC when it is sent to the printer.