

Welch Allyn®

Surveyor™ Central

5.X.X

SERVICE MANUAL

Manufactured by Welch Allyn, Inc., Skaneateles Falls, NY U.S.A.



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

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GENERAL INFORMATION

Service Manual Purpose

The purpose of this manual is to supply information to authorized service personnel so they can properly maintain the Surveyor Central 5.x.x system. Information for peripheral devices, such as printers should be found in manuals supplied with equipment or by contacting original manufacturer. This manual is intended to function as the primary guide to preventive maintenance and electrical repairs considered field repairable for the Surveyor Central system.

Manufacturer's Responsibility

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

- System installation and assembly operations, extensions, readjustments, modifications or repairs are carried out by personnel authorized by Welch Allyn, Inc. only.
- The device is used in accordance with the instructions for use.
- The device is correctly maintained according to the standards authorized by Welch Allyn, Inc. using original spare parts.
- The device is used with compatible accessories and supplies. Contact Welch Allyn or one of its affiliates for a current list of compatible accessories and supplies.
- The electrical installation of the relevant room complies with the requirements of appropriate regulations.

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. This manual must be kept in a safe place to prevent its deterioration and/or alteration. The user and Welch Allyn, Inc. authorized personnel must have access to this manual at any time. The user of this device must periodically check the transmitters and monitors, their functionality and the integrity of their accessories.

Equipment Identification

Welch Allyn, Inc. equipment is identified by serial and part numbers on the side, back, or bottom of the device. Care should be taken so that these numbers are not defaced.

The device product label is applied showing the unique identification numbers along with other important information printed on the label.

The serial number format is as follows:

YYYWSSSSSS

YYY = First Y is always 1 followed by two-digit Year of manufacture

WW = Week of manufacture

SSSSSS = Sequence number of manufacture

The product label and UDI label (when applicable) are applied to work station.

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Other Important Information

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Notice to EU Users and/or Patients:

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

Disposal

This product and its accessories must be disposed of according to local laws and regulations. Do not dispose of this product as unsorted municipal waste. For more specific disposal information see www.welchallyn.com/weee.

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.

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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.

Safety Regulations

Surveyor Central cannot be classified as Medical Electrical Equipment according to the definition of safety standard IEC 60601-1. The Surveyor Central, together with all accessories that have a physical or logical connection with it, forms part of a Medical Electrical System. The Surveyor Central complies with various safety and performance regulations as mentioned in Appendix E.



WARNING(S)

- This manual gives important information about the use and safety of this system. Deviating from operating procedures, misuse or misapplication of the system, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the system.
- Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this system. Before attempting to use this system 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 system. Contact Welch Allyn service for additional training options.
- The Surveyor Central is not designed to be used in the environment where the patient is undergoing a medical procedure as defined in IEC 60601-1 (1.5 m from the patient).
- The Surveyor Central is not battery operated. For uninterrupted use, an appropriate uninterruptible power supply (UPS) is required. The WiFi network (telemetry) as well as any active network components such as switch and firewall should also have the capability to remain operational in cases of general power outages. The Surveyor Central is designed to continue operation with the last stored settings after a power interruption, however, loss of stored data is possible if power is interrupted to the system that stores the data. When using a backup power source such as a UPS, periodically check it to ensure it is properly functioning per the manufacturer's recommendations and specifications.

- In order to be safely used, all accessories (such as monitors, printers, data network, etc.) must be compatible, and comply with all safety and EMC regulations that apply to them according to their intended use; for use in Europe, these accessories should be CE marked.
- The various parts of a Surveyor Central monitoring system (Telemetry receiver computers, control and display computers, storage computers, printers, or bedside monitors) are all connected through a specific Ethernet data network. This network must be installed according to all applicable standards and may only be logically or physically connected to the outside world through a specific routing device available from Welch Allyn. Any other data path can lead to serious security risks and interruptions of monitoring. Other devices must not be connected to the Surveyor data network.
- Connection of the Surveyor Network along with its associated transmitters and monitors to the IT Network in a healthcare delivery organization may carry risks to patients, operators as well as 3rd parties. Such risks must be carefully assessed and mitigated. The IEC 80001-1:2010 standard provides guidance to the healthcare delivery organization for carrying out such risk assessment and mitigation. Changes to the IT Network can also introduce new risks which should be carefully assessed and planned.
- In the case of a Surveyor Central system with additional control stations for display and control of the same patient channels in multiple locations, silencing or suspending of alarms will cause the alarm to be silenced or suspended at all the locations. Be certain that alarms are silenced or suspended by the clinician having direct responsibility for care of the given patient.
- Cleaning must be performed with the system turned off. Let all parts dry well before turning the power back on.
- Install all computer equipment with adequate space around ventilation vents. Clean and remove accumulated dust on ventilation openings, and also remove dust regularly from the inside of the system. The last operation must be performed by adequately trained and authorized personnel, and with the system turned off.
- Install the external USB connected speakers that generates the alarm sounds in such a way that the sound can be heard adequately in the appropriate areas. Do not unplug the USB speakers from the computer as this may cause the interruption of audible alarm.
- The Surveyor Central provides an alarm volume adjustment. Be sure to set the volume at a level that alarms can be heard above the ambient noise level in the environment of use. Setting alarm volumes too low can impede recognition of alarm signals.
- The hardware watchdog device is connected to the computer with a USB cable and has its own power supply. Mount it in such a way that the sound can be heard adequately in the appropriate areas. Test regularly by temporarily removing the USB plug while the central station power is turned on.
- The Surveyor Central must be connected to a properly grounded power terminal, and the electrical installation must comply with the local safety requirements for the environment where it is used.
- The Surveyor Central requires more than one mains outlet. Fix multi-socket outlets properly, do not leave them on the floor, and organize the cabling in such a way that normal work is not hampered and safety is not compromised.
- Regularly check all mains power cables for damage and proper connection. Do not use equipment with a damaged power cord.

- The Surveyor Central components are not waterproof. Avoid spillage of liquids from penetrating the system or submersion of components and transmitters into a liquid. In case of accidental spillage, turn device off and let dry thoroughly.
- The various manufacturers of accessories provide separate user manuals (e.g., monitor, laser printer, Surveyor S12/S19, Surveyor S4, patient cables, electrodes). Read these manuals well and refer to them for specific functions. It is recommended to keep all manuals together. Refer to these manuals for a list of approved accessories. When in doubt, contact Welch Allyn.
- Every hardware or software modification has to be made by Welch Allyn authorized and trained technical personnel.
- Do not disassemble the equipment as hazardous voltages may be present within. Contact Welch Allyn or an affiliated service representative for repairs.
- Technical and service documents are available upon request.
- Always turn the system off before connecting or disconnecting any cables.
- Do not use the system in places that are susceptible to explosion hazard or in the presence of flammable gases.
- Do not use the system in the presence of Magnetic Resonance Imaging (MRI) equipment and tomography equipment.
- Do not insert a bootable CD/DVD on the Surveyor Central computers. Do not run any program from CD/DVD or USB memory sticks. These I/O devices should only be used for export and import of patient ID formats, profiles and protocols.
- Surveyor Central computers contain a small lithium battery for maintaining clock and BIOS settings which should normally last the lifetime of the system. If the battery needs to be replaced, be sure that it is done by qualified personnel and with a battery of the same type.
- Surveyor Central software has been extensively tested and clinically validated. Several protection mechanisms against software errors have been built into the Surveyor Central; however, in the unlikely event of a failure of the software or the computer processor, the electronic (hardware) “watchdog” of the Surveyor Central sounds a continuous loud beep and the Central station has to be power-cycled to remove this. Please inform Welch Allyn service personnel for further troubleshooting should this continuous loud beeping occur.
- Surveyor Central hardware has been carefully selected for reliability; however, in mission critical situations, it might be advisable to have a backup system available at short notice. This also includes accessories such as patient transmitters and monitors which, by nature and way of use, can be more prone to failure.
- Installation and connection to data networks must be performed by properly trained personnel, authorized by Welch Allyn, Inc.
- To maintain designed operator and patient safety, use only parts and accessories supplied with the system and available through Welch Allyn, Inc.
- The equipment described in this manual has an expected lifetime of five years from the date of manufacture. Operation beyond this expected life may not meet specifications. This lifetime is only valid if devices are used according to the instructions in this manual and associated manuals provided with the equipment.

- The system captures and presents data reflecting a patient's physiological condition that when reviewed by a trained physician or clinician can be useful in determining a diagnosis. However, the data should not be used as a sole means for determining a patient's diagnosis. The system is optionally equipped with Welch Allyn's VERITAS™ 12-lead resting ECG interpretation algorithm. When this option is enabled, the VERITAS ECG algorithm can provide an over-reading physician with a silent second opinion through diagnostic statements output on the ECG report. For additional information on the Welch Allyn VERITAS 12-lead resting ECG interpretation algorithm, please refer to the Physician's Guide to ECG Interpretation.
- 12-lead ECGs acquired through Surveyor Central or attached monitors will normally use a modified lead system with the limb electrodes positioned on the torso. Although this is a generally accepted practice (e.g., in stress testing), the different electrode positions can cause morphology changes on the ECG, thus influencing their interpretation. Most frequently seen differences are a vertical and rightward axis shift, minor changes of evidence of old inferior infarction and changes in the T-wave in the limb leads. All 12-lead ECGs printed with Surveyor Central have a warning message that alerts the physician that the ECG might have been acquired with torso positioned limb leads. It is recommended that you place the electrodes as close as possible to the normal limb positions avoiding the possibility of causing artifact. The right arm and left arm electrodes should be placed on the clavicles as close as possible to the arms. The left leg electrode should be placed as close as possible to the left leg without subjecting it to the possibility of motion artifact.
- The minimum amplitude for detecting QRS complexes is user selectable between 160, 300 and 500 μV . A low value of this limit has the risk of detecting P waves as QRS complexes in the case of atrio-ventricular block; however, a high value might lead to false cardiac arrest alarms if the QRS amplitude is low in all leads. Therefore, the user is encouraged to select detection leads with amplitude of at least 1 mV and set the minimum QRS amplitude at 300 μV .
- During periods of lead fail and when a reduced lead set is used for patient monitoring, 12-lead resting ECG interpretation cannot be reliably used in determining a diagnosis.
- When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise cannot be reduced by proper procedures.
- The quality of the signal produced by the system may be adversely affected by the use of other medical equipment connected to the patient including, but not limited to, defibrillators and ultrasound machines.
- If the system or one of its subsystems become inoperable during monitoring, a medium or low priority type alarm sounds and a message is displayed on the screen. In case of hardware or software failure that causes the sound generator or display subsystem to fail, the hardware watchdog unit generates a continuous beep. Periodic checks of the monitoring screen are recommended to ensure proper functioning.
- The LCD supplied with the Surveyor Central has a separate power switch and power-on indicator. If no image appears on the screen, check the LCD power indicator. Alarm sounds are not affected by the status of the LCD. Do not connect a sound-capable display monitor such as a LCD TV to the Surveyor Central.
- The on/off switch of the Surveyor Central is deactivated and can only be used for emergency power down by depressing it for a period greater than 4 seconds. Normal shutdown of the Surveyor Central should be done by using the password-protected configuration window.
- Do not use excessive force on any of the connection cables and handle all accessories with care.
- Various alarm conditions require operator set limits that vary per patient. For telemetry monitoring, Surveyor Central supports the selection of appropriate alarm profiles when a patient is admitted. The operator should check these settings after each patient admission to ensure whether the chosen alarm limits are appropriate for the individual patient. Inappropriate alarm limits render the alarm system useless.

- Saved profiles are only applicable to the type of cable and detection leads in use when the profile was defined. If another type of cable is used with a saved profile, the default detection leads will be utilized.
- In any single environment such as an intensive care unit or cardiac operating theater, a potential hazard can exist if different alarm preset values are used for the same or similar equipment.
- Portable and mobile RF communications equipment can affect medical electrical equipment or systems as well as the Surveyor Central and its accessories.
- Surveyor Central alarms can only be silenced and not reset. This means that visual representation of an alarm condition remains present after an operator silenced action until the alarm condition disappears (unless obscured by another, higher priority, alarm). The auditory alarm signal does not re-activate after a silence action if the alarm condition remains the same. As soon as the alarm condition of a silenced alarm goes away, the alarm can be reactivated.
- The Surveyor Central alarm system can be globally disabled or suspended for a period of time for a patient. The selection between disabling and suspending, as well as the suspension duration, can be set in the password-protected system configuration page. A clear visual indication of this condition is present in the patient window, and a reminder signal sounds every three minutes. Any technical alarms will be visually presented on the screen, regardless of the alarm disabled state. In this configuration the technical alarms will not be audible.
- The intended use of Surveyor Central Repeater is to repeat waveforms, parameters and system status of selected patients monitored by Surveyor Central in order to enhance workflow for medical personnel. Surveyor Central Repeater does not produce audible alarm signals and may not be used to substitute any alarm functions of Surveyor Central.
- This manual applies to the most recently manufactured system, with respect to software release and hardware configuration. Whenever used for software upgrades on previously installed equipment, some technical specifications or labels may not be respected, whereas functions and instructions for use of the system are always valid. This user manual reflects software version 5.1.0.
- This product complies with relevant electro-magnetic interference, mechanical safety, performance, and biocompatibility standards. However, the product cannot completely eliminate potential patient or user harm from the following:
 - •Harm or device damage associated with electro-magnetic hazards,
 - •Harm from mechanical hazards,
 - •Harm from device, function, or parameter unavailability,
 - Harm from misuse error, such as inadequate cleaning.
- The device and IT Network the device is connected to should be securely configured and maintained per the IEC 80001 standard, or an equivalent network security standard or practice.

The following warnings concern telemetry monitoring:

- Electrostatic discharges may generate short interference on the ECG tracings.
- WiFi Telemetry: The Surveyor S4 utilizes standard WiFi telemetry per the IEEE 802.11g/n standard. The WiFi network supporting the Surveyor S4 and for use with the Surveyor Central must be installed and tested in accordance to Welch Allyn's guidance and network requirements. Also refer to Welch Allyn's Manufacturer Disclosure Statement for Medical Device Security (MDS2) documents for the Surveyor Central and Surveyor S4. Welch Allyn and/or 3rd party partners are available to perform network site surveys and audits to confirm the suitability of the facility's WiFi network for use with the S4 mobile monitor and connection to the Surveyor Central and its Surveyor Network.
- The system was not designed to be used with high frequency (HF) surgical devices.

- Use of transmitters and monitors may be restricted in some countries; see the transmitter's and monitor's user manuals for details.
- Consult the Surveyor S12/S19 and Surveyor S4 user manuals for more information regarding the patient cable, electrode recommendations, cleaning, maintenance, channel frequencies, precautions to take during patient defibrillation, and other warnings.

The following warnings concern pulse oximetry (SpO₂) telemetry monitoring:

- Pulse oximetry sensors must be checked a minimum of every 4 hours and moved to a new site as necessary.
- Pulse oximetry sensors are susceptible to high ambient light interference including ambient photodynamic therapy. Shield the sensor area as necessary.
- SpO₂ measurement may be adversely affected by dyes (e.g., methylene blue, indocyanine green, indigo, carmine, fluorescein) introduced into the bloodstream.
- Any condition that restricts blood flow such as the use of a blood pressure cuff or extremes in systemic vascular resistance may cause inability to determine accurate SpO₂ readings.
- Certain conditions such as physical movement (patient and imposed motion); diagnostic testing; low perfusion; electromagnetic interference; electrosurgical units; dysfunctional hemoglobin; and inappropriate positioning of the pulse oximeter sensor may result in pulse oximetry readings that are unreliable.
- SpO₂ signal inadequacy is indicated by error messages displayed on the LCD of the transmitter and by alarms generated at the Surveyor Central system for signals coming from the transmitter.
- The performance of the monitor may be compromised by excessive motion.
- Nail polish and/or artificial fingernails can affect the accuracy of pulse oximetry and should be removed.
- The pulse oximeter equipment is calibrated to display functional oxygen saturation.
- Functional SpO₂ testers (simulators) are useful to measure how accurately a particular monitor is reproducing the calibration curve but cannot be used to assess the accuracy of a type of probe or monitor. If there is independent demonstration that a particular calibration curve is accurate for the combination of a pulse oximeter monitor and a pulse oximeter probe, then a functional tester can measure the contribution of a monitor to the total error of a monitor/probe system. The functional tester can then measure how accurately a particular pulse oximeter monitor is reproducing that calibration curve.
- If no SpO₂ or pulse rate is present, alarm conditions are provided at the Surveyor Central system. There is no alarm condition provided at the transmitting device.
- For additional instructions and warnings, refer to the user manual of the transmitting device.

The following warnings concern heart rate for telemetry monitoring:

- Heart rate indication is usually not affected by ventricular or supraventricular arrhythmias or irregular heart rates. Heart rate is calculated over 16 beats at rates over 40 bpm and 4 beats at lower heart rates. This results in a response time of 9 seconds or less when the heart rate changes suddenly from 80 bpm to 40 or 120 bpm, as measured according to IEC 60601-2-27.
- High heart rate and low heart rate alarms cannot be disabled.
- Tall and peaked T-waves may affect QRS detection resulting in doubled heart rates. Surveyor Central rejects tall T-Waves less than or equal to 230% of a 1 mV QRS measured according to IEC 60601-2-27.
- The heart rate meter correctly detects all beats of the alternating beat type waveforms considered in IEC 60601-2-27, Figure 201.101, patterns A1-A4, if the QRS amplitudes exceed the minimum detection threshold set by the user.
- Time to low heart rate, high heart rate and asystole, as measured according to IEC 60601-2-27, is less than 10 seconds.
- Heart rate indication is not reliable during episodes of ventricular fibrillation.

- The summarized performance of the QRS recognition and classification algorithm on standard databases, as defined by ANSI/AAMI EC 57, is as follows:

	MIT Database
Performance Measures	Welch Allyn
QRS Detection Sensitivity %	99.93
QRS Detection Positive Predictivity %	99.87
PVC Detection Sensitivity %	95.13
PVC Detection Positive Predictivity %	97.04
PVC Detection False Positive Rate %	0.220

	AHA Database
Performance Measures	Welch Allyn
QRS Detection Sensitivity %	99.78
QRS Detection Positive Predictivity %	99.91
PVC Detection Sensitivity %	93.15
PVC Detection Positive Predictivity %	98.40
PVC Detection False Positive Rate %	0.154

- Because of noise, artifact and the many different physiological manifestations of the ECG signal, it is inevitable that some beats are not detected or correctly classified by the system. The user is advised not to rely completely on automatic alarm systems for the monitoring of critical patients.
- Excessive patient movement could interfere with the operation of the system.
- Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
- If the ECG amplifier input is out of normal operating range, the display will indicate a lead fail for the lead(s) where this condition is present and if the signal is being displayed or printed, the respective lead(s) will print out as square waves. A lead fail alarm is generated on the Surveyor Central.

The following warnings concern pacemaker patients for telemetry monitoring:

- 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. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.
- With the Surveyor S4, all pacemaker spikes are rejected per the IEC 60601-2-27 standard (0.1 - 2 ms duration, 2 - 700 mV amplitude). Signals are recognized as pacemaker spikes when they have a slew rate over 4 V/s, as measured according to the IEC 60601-2-27 standard. Abnormally high or wide pacemaker spikes might be recognized as QRS if their amplitude and pulse width exceed these values. With the Surveyor S4 when used with the 4-wire, 5-wire or 10-wire ECG cable, all pacemaker spikes are rejected per the IEC 60601-2-27 standard (0.1 - 2 ms duration, 2 - 700 mV amplitude). Signals are recognized as pacemaker spikes when they have a slew rate over 4 V/s, as measured according to the IEC 60601-2-27 standard. Abnormally high or wide pacemaker spikes might be recognized as QRS if their amplitude and pulse width exceed these values. With the Surveyor S4 when used with the 3-wire ECG cable, pacemaker spikes are not rejected consistently. For this reason, do not rely upon heart rate meter ALARM SIGNALS, when using a 3-wire cable.
- Consult the Surveyor S12/S19 User Manual for a description of its pacemaker spike rejection capabilities.
- The Pacemaker Rejection software can be deactivated by the user (see the Patient Data section of this manual). This should not be done for patients with a pacemaker or suspected to have a pacemaker implanted because this can lead to a heart rate indication and failure to alarm for cardiac standstill.
- Other than the influence on beat detection as stated above, there is no known safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the system.

Notes

- Surveyor Central contains electronic records including ECG's which can be exported to other applications. The Surveyor Central system can be part of a system that is compliant with the electronic records requirements of part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11) as stipulated by the US Food and Drug Administration's (FDA). The user of the Surveyor Central system must ensure full compliance to this as required.
- The Surveyor Central system implements certain features such as username/passwords and audit trails. By-design, the system is accessible and available for use upon power-up. The facility deploying and using the system is responsible for ensuring appropriate safeguards are put in place to protect patient health information (PHI). This includes a mixture of physical and IT-based mechanisms to secure PHI from unauthorized access. The Surveyor Central Station including printers generating reports must be placed in a physical location that is secure (e.g., nurse's station). Surveyor Review and Repeater stations may be placed in less secure locations but must implement proper username/password access policies as required.

EQUIPMENT SYMBOLS AND MARKINGS



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.



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 Hillrom for delivery within 7 calendar days.



Direct Current (DC) power input



Indicates compliance to applicable European Union directives



Universal Serial Bus (USB) port



Do not dispose as unsorted municipal waste. Requires separate handling for waste disposal according to local requirements.



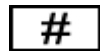
Output terminal



Network connection



ON (Power)



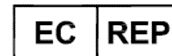
Model Identifier



Reorder Number



Medical Device



Authorized representative in the European Community



Manufacturer



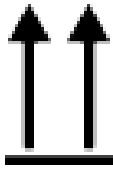
Serial Number



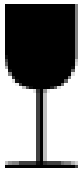
Global Trade Item Number



Keep away from sunlight



This way up



Fragile



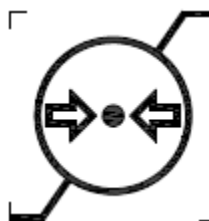
Keep dry



Temperature limit



Humidity limitation



Atmospheric pressure
limitation

Product Lifetime

Welch Allyn intends to support the Surveyor Central Processing Unit, monitors, and transmitters, for not less than three (3) years beyond the date of the last unit produced of that revision, or for as long as parts, accessories and expertise are available from our vendors, subject to last time buys and technology obsolescence.

ELECTROMAGNETIC COMPATIBILITY

The Surveyor Central Station is a patient monitoring central station using off-the-shelf ITE equipment such as workstation PC, server and peripheral equipment. All ITE equipment provided with Surveyor Central Station are compliant to the applicable Electromagnetic Compatibility Standards for Information Technology Equipment (ITE) including:

- EN 55032:2012 (equivalent to CISPR 32:2012) Class A or Class B for Emissions.
- EN 55024:2010 (equivalent to CISPR 24:2010 for Immunity.
- EN 61000-3-2:2014 for Harmonics.
- EN 61000-3-3:2013 for Flicker
- Federal Communication Commission (FCC), Code of Federal Regulations (CFR), Title 47, Part 15.



WARNING: The Surveyor Central is not designed to be used in the environment where the patient is undergoing a medical procedure as defined in IEC 60601-1. Therefore, to guarantee Electromagnetic compatibility do not place the Surveyor Central Station in the patient environment.

SYSTEM OVERVIEW

System Description

The Surveyor Central can perform telemetry monitoring using the Surveyor S4 integrated with the healthcare delivery organization's WiFi network infrastructure. The Surveyor Central is also designed to communicate with the Surveyor S12/S19 multi-parameter patient monitors.

Its intended functions include:

- Real-time, 3-wire (1-lead), 5-wire (7-lead) and 10-wire (12-lead) diagnostic ECG signal display
- Real-time SpO₂ plethysmographic waveform display
- Automatic monitoring of arrhythmias, SpO₂ values, and ST changes including one or more displayed waveform channels for each patient
- Visual and audible alarms of events, arrhythmias, and set parameters with adjustable priorities
- Averaged and reference QRS complexes
- Graphical trend review
- Single lead or any combination of leads up to 12 for ECG rhythm and report printing
- ECG signal and SpO₂ data storage with optional full-disclosure storage and review
- When the patient device is a Surveyor S12/S19 monitor, additional parameters may include non-invasive blood pressure (NIBP), impedance respiration, invasive pressures (P1-P4), Temperature (T1, T2), end-tidal and inspired CO₂, and cardiac output (CO).

Through telemetry, patients using ambulatory transmitters are monitored while moving in a designated area. To guarantee proper signal transmission in various situations, install an antenna network as per facility requirements.

The Surveyor Central Station communicates with the Surveyor S12/S19 patient monitors through a Local Area Network (LAN) interface. The Surveyor Central network can distribute patient data to one or more Surveyor Central control stations in a single or dual display mode.

Each Surveyor Central receiving workstation will acquire data. Connect multiple Surveyor workstations to the same Surveyor Central network to allow real-time patient monitoring in a variety of different system configurations (see following page).



Figure 1 – An example of Surveyor Central configured with dual displays.

Control, viewing, receiving signals, and data storage are all possible on a single Surveyor Central workstation. Control, viewing, receiving signals, and data storage can also be achieved using separate workstations for each function--or a combination of functions--on the Surveyor Central network. Networked printers are used for automatic or manual printouts of 12-lead ECG, ECG rhythm, plethysmographic waveform with % SpO₂ and pulse rate, and reports.

An optional redundant storage server is available for increased storage capacity as well as storage to duplicate data disks when continuous and complete ECG capture is critical. This is valuable for institutions that collect ECG data for research purposes. This capability may also be important for other medical facilities.

The Surveyor Central system provides the means for users to manage patient records with associated patient demographics and assign each to a particular patient monitor or telemetry system for obtaining physiological information. Physiological data obtained from patient monitors and telemetry devices are viewable and stored continuously with a minimum storage timeframe of 72 hours. Alarm monitoring and management, including definition of alarm limits, as well as data trending and reporting are available. Full disclosure supports review of the data on a particular patient including review of 12-lead ECG waveforms and other data and waveforms for obtained parameters.

Surveyor Central with WiFi telemetry

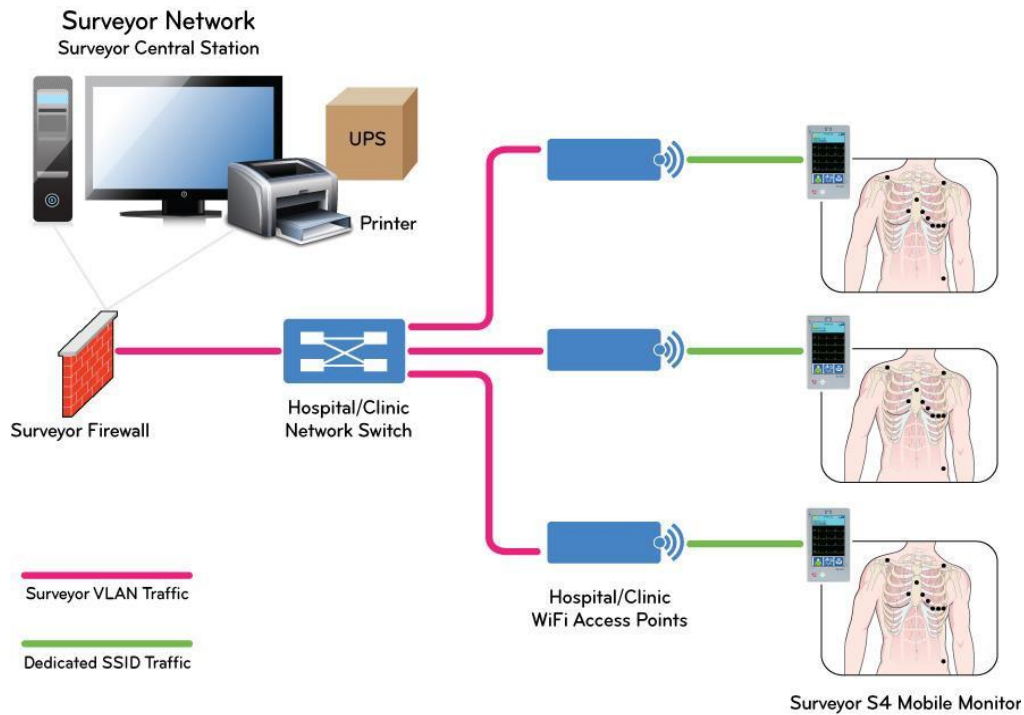


Figure 2 - A Surveyor Central configuration with WiFi telemetry using Surveyor S4 mobile monitors.

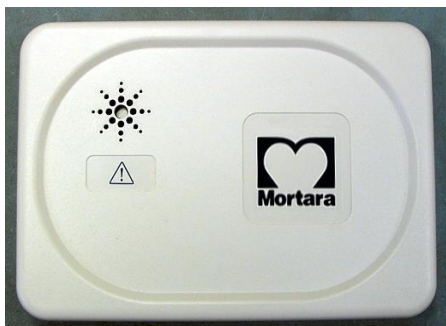
Surveyor Central with Multiple Control of Same Channels

Additional control stations are available for display and control of the same patient channels in multiple locations. Channel allocation for multiple control stations is defined during installation and setup.

Surveyor Central USB-WATCHDOG

Surveyor Central is intended for continuous use. A Watchdog is externally connected to a USB port and emits a loud and continuous audible alarm in case of system failure. A Watchdog is a required and necessary part of every control workstation.

Top view



Side connections



Figure 3 - Top and side view of the Surveyor Central USB watchdog device.

Optional System Components

- **Single color display:** A single 24" LCD display optimally supports up to 16 or a maximum total of 32 telemetry and patient monitoring slots.
- **Dual color display:** A 24" dual LCD display optimally supports up to 32 or a maximum total of 64 telemetry and patient monitoring slots.
- **Single, touch-enabled color display:** A single 24" LCD display optimally supports up to 16 or a maximum of 32 telemetry and patient monitoring slots; with touchscreen function.
- **Keyboard/mouse switch:** Allows one keyboard and mouse to control up to 4 nodes, with their displays configured to seamlessly produce one large virtual desktop.
- **Surveyor Central control station:** A workstation with single or dual display on the Surveyor Central network for purposes of controlling and viewing a set of monitored channels at a designated location within the facility.
- **Surveyor Central receiving station:** A workstation connected to the healthcare delivery organization's WiFi network through a firewall router for the purposes of receiving transmitted signals from Surveyor S4. As required, the receiving station produces a set of channels for viewing or storage at another location on the Surveyor Central network.
- **Surveyor Central receiving and control station:** A workstation with single or dual display connected to the transmitters and monitors for purposes of receiving transmitted signals to produce, display, and control a set of monitoring channels. Data storage is accomplished at another location on the Surveyor Central network.
- **Redundant data storage:** Stores real-time data and simultaneously copies the data to a set of Redundant Array of Independent Disks (RAID) for increased storage capacity and data security in situations where complete data collection is critical. All system data storage for workstations on the Surveyor Central network is performed at this networked server when it is a component of the Surveyor Central.
- **Surveyor Central repeater station:** A display station where monitoring channels are repeated and can be displayed, printed, and reviewed. Alarms are visual only and are not audible or controlled at the repeater station.
- **Network printer (print server):** The printer must be plugged into the AC power outlet through the appropriate power cord that is in compliance with local regulations. Please refer to the printer manufacturer's user manual for information, warnings, commands, and intended use.

System Software Options

- Full disclosure for continuous data storage:** All patient monitoring data is available for review when this option is enabled. The storage amount is dynamic and relies on the number of channels utilized in relation to the size of the storage space. Each day of a patient's data is equal to approximately 0.5 GB. Divide number of storage days by number of monitored patients to calculate number of days for each monitored patient (i.e., $600 \text{ days of storage} \div 10 \text{ monitored patients} = 60 \text{ days per patient}$). This option also allows off-line archive to a network directory or DVD media. Data can be acquired by Welch Allyn's HScript™ Holter analysis system for further review, rhythm quantification, Holter reporting, and/or 12-lead ECG collection which can then be exported in XML or Unipro format. When this option is not enabled, one minute of ECG data surrounding each event or alarm is stored for review, ECG printing, and export.
- Protocol manager:** Only available for Telemetry channels. Allows the clinician to design automatically-timed reminder events, automatically generate printed ECGs, and/or export resting 12-lead ECGs. This is particularly useful to clinicians that perform ECG data collection and must remember to execute certain functions at specific times. The application allows the clinician to program the times for such events to automatically occur. Several different protocols can be designed and the desired protocol can be selected during the patient monitoring sessions. Protocols can also be programmed in phases started by the Surveyor Central station user or by pressing the call button on the transmitter.
- Extended arrhythmia and 12-lead ST monitoring:** In addition to standard lethal arrhythmia events and alarms, this option allows the clinician to automatically print and capture ventricular ectopy, rhythm patterns, and QRS changes as well as pacemaker failure events. This feature also allows averaged 12-lead ECG display for comparison of the reference ECG superimposed on the current ECG. The reference ECG is used for ST change alarms. Note that not all extended arrhythmias are available with S12/S19 patient monitors.
- Resting ECG interpretation:** Enables global ECG measurement including QT/QTc calculation and 12-lead ECG interpretation utilizing Welch Allyn's VERITAS algorithm. 12-lead ECGs can be exported in Unipro format to a network directory or directly to Welch Allyn's E-Script™ data management system. This option is required to enable the ability to use and define E-Script custom ID formats. This feature is optional with telemetry only monitoring channels. This feature is always included with Surveyor S12/S19 patient monitoring or a mix of telemetry and S12/S19 patient monitoring.
- Review station:** Enables patient data review in the Surveyor Central from the online database, as well as patient monitoring data archived from the database to external media. The (separate) Resting ECG Interpretation option is required to enable global measurement and 12-lead ECG interpretation on archived records.

The Surveyor Central review station screen layout is similar to the Surveyor Central review screen in dual-display modality and has the same functionality as the Surveyor Central review features including printouts and export. When networked to the Surveyor Central database, it is possible to initiate archive of patient monitoring data. Please refer to the Surveyor Central Review Station user manual (PN 9515-169-75-ENG) for more detail.

Surveyor S12 and S19 Patient Monitors

The Surveyor S12/S19 patient monitors are multiparameter patient monitors designed to acquire physiological waveforms and parameters, and to transmit this data to the Surveyor Central monitoring station.

Please refer to the Surveyor S12/S19 patient monitor user manual (PN 9515-183-51-ENG) for details.



Figure 4 - Surveyor S19 Patient Monitor shown with optional printer and wall mount.

Surveyor S4 Mobile Monitor

The Surveyor S4 is a small, lightweight mobile monitor with a touchscreen designed to acquire ECG and SpO₂, and to transmit this data to the Surveyor Central monitoring station via a 802.11g/n wireless network.

Please refer to the Surveyor S4 User Manual (PN 9515-190-50-ENG) for details.



Figure 5 - Surveyor S4 Mobile Monitor

Surveyor Central with Wireless Access Points

Transmission from and to the Surveyor S4 is via the healthcare delivery organization's WiFi wireless network used for patient data transmission and other system-level communications. When configured with optional 10-wire ECG, the S4 provides continuous 12-lead ECG transmission. Refer to the diagram in this section.

Surveyor Central Network

The network for the Surveyor Central allows for the connection and exchange of data between the system components. Ethernet cable is used to connect all devices to the multi-port switch through an internal or external wall connection. All devices are outside of the patient area.



WARNING: Do not connect the Surveyor Central Network to computers, devices other than those specified by Welch Allyn, or the Internet, as system operation may be impaired. Consult Welch Allyn or one of its affiliates for information on devices that are approved for use on the Surveyor Central Network.

Surveyor Central's security router is used to isolate the system from the institution network. A secure firewall router is used for any repeater stations or review stations that are located outside of the Surveyor network. Other applications that access Surveyor Central such as Surveyor Import for Holter analysis and remote service support are networked in this way.

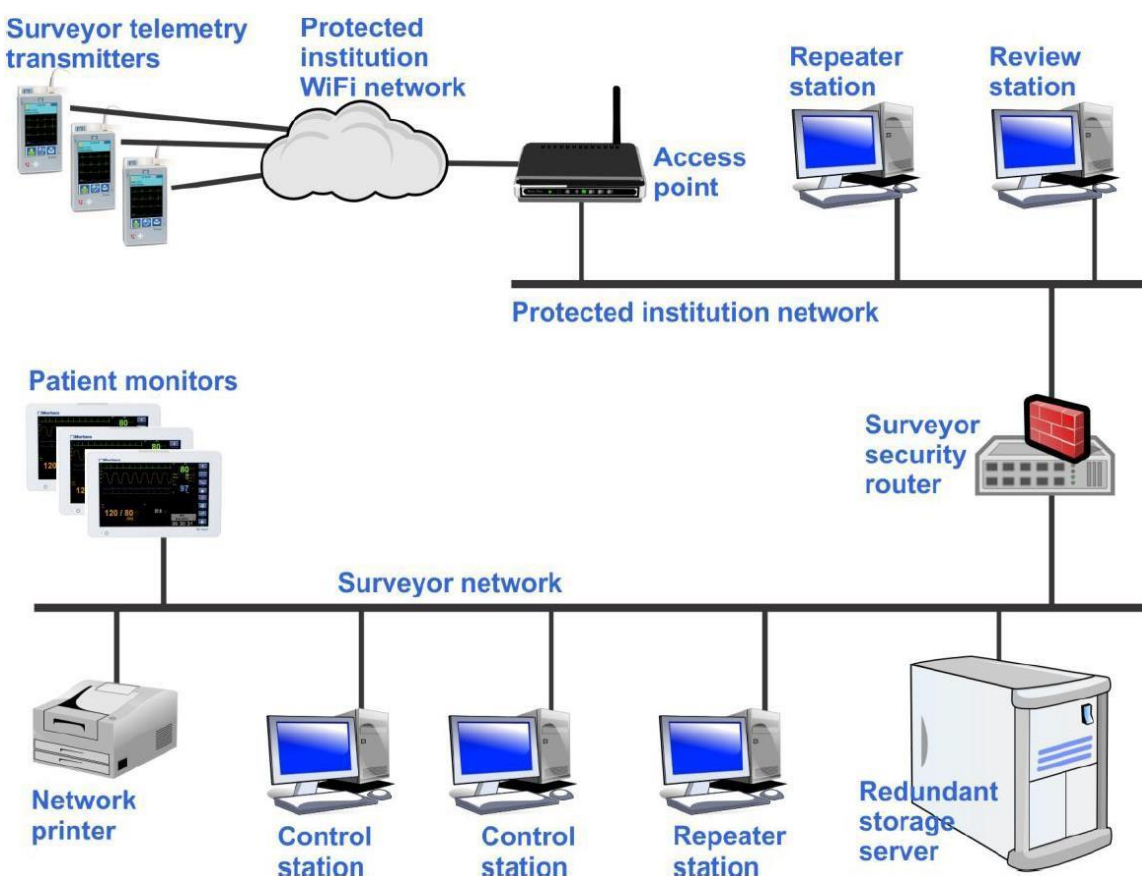


Figure 6 - The Surveyor Central network.

The Surveyor Central repeater station is available as either a dedicated model or standalone software application.

- The dedicated model is installed within the Surveyor network and does not allow user access to any other Microsoft® Windows® programs. It will automatically start when the Surveyor Central is started, the same as any other dedicated node on the system.

- The repeater standalone application contains the same software and can be safely used on a computer on the institution network that meets the minimum specifications listed below and where there is access to the Surveyor security router through LAN or WLAN connection.
 - Microsoft Windows 10 (64-bit only)
 - 4 GB RAM
 - 250 GB Hard Disk Drive
 - DVD/CD Drive (for software installation)
 - Fast Ethernet NIC
 - 1920 x 1080 Graphics Resolution

In addition, the repeater standalone application can be safely used on a suitable tablet PC's that meets the minimum specifications listed below and where there is access to the Surveyor security router.

- Microsoft Windows 10 (64 bit only).
- Intel® Core i3 (7 gen) 7130U
- 4 GB RAM
- 128 GB SSD
- 10.1"
- 1440 × 900 Graphics Resolution

Facility infrastructure requirements/compatibility.

NOTE: In order to meet the declared Repeater standalone application performances, no more than two Repeater standalone applications, with eight patients under monitoring, must be connected to the same access point.

NOTE: In order to meet the declared Repeater standalone application performances, no more than nine Repeater standalone applications must be used at the same time.

NOTE: When connected to Surveyor Central through WLAN connection, the Repeater standalone application performances depend on the customer WLAN connection and its traffic.

The Surveyor Central review station can be networked to the institution network with connection to the Surveyor security router when access to Surveyor Central's patient database is desired for remote review. The review station can also be installed as a stand-alone and used for review of archived patient monitoring records from media external to the Surveyor Central. Please refer to the Surveyor Central user manual (PN 9515-169-90-ENG) for more detail.

Item Identification

Overall System Part Numbers

DESCRIPTION	ITEM NUMBER
CENTRAL SYSTEM	SCSYS-XXX-XXXXX
CONTROL NODE	SCNODE-XXX-XXXXX
REDUNDANT STORAGE	SCNODE-XXX-XXXXX
REVIEW NODE	SCREV-XXX-XXXXX
REPEATER NODE	SCREP-XXX-XXXXX

Computer Specific Parts

Server

Description	ITEM NUMBER
USB Watchdog Assembly	30012-017-50
Watchdog Power Supply	4101-007
HP PROLIANT ML350P GEN8 SERVER	9906-039-01
POWER SUPPLY 460W	9906-039-11
Hard Drive SATA 1TB	9906-040-21
HARD DRIVE 450GB 6G SAS 15K SC ENTERP	9906-039-31
HP PROLIANT ML350P GEN9 SERVER	9906-044-01
POWER SUPPLY 500W	9906-044-11
HARD DRIVE 500GB 12G SATA 7.2K LFF 3.5	9906-044-21
HRD DRV 450-600GB 12G SAS 15K SC ENT	9906-044-31
HP PROLIANT DL380 GEN10 SERVER	728930
HP PROLIANT DL380 GEN10 SERVER - New Processor & 16GB RAM (same drives and PS)	774278
G10 HPE Midline Hard Drive 1TB SATA 6GBs	749836
G10 600GB SAS 12G Ent 15K SFF SC Dig HDD	749837
G10 HPE Power Supply 800 Watt 809VA	749838
HP DL380 GEN10 SERVER – w/Image	SERV-774278

Standalone Central With Storage:

Description	ITEM NUMBER
PC WORKSTATION Z240	9906-045-01
POWER SUPPLY 280W Z240	9906-045-11
500GB HARD DRIVE 7200 RPM SATA	9906-045-21
DRIVE, GOLD 1TB SATA ENTERPRISE	728550
SYSTEM BOARD Z240 TOWER HP	9906-045-31
8GB RAM DDR4-2133 ECC	9906-045-51
HP Z2 G4 Dual HDD Workstation	749817
Z2 HDD 1 TB 7200RPM SATA Ent 3.5 in (both drives are identical)	749846
Z2 RAM 8GB DDR4 2666 DIMM ECC	749847
Z2 Keyboard USB Bus Slim US	749849
Z2 TWR G4 90 500W Chassis Power Supply	749850
Z2 Mouse	749851
Z2 PC Motherboard	749852
USB Watchdog Assembly	30012-017-50
Watchdog Power Supply	4101-007

Workstation

Description	ITEM NUMBER
CPU WORKSTATION Z240	9906-045-01
HP Z2 G4 Dual HDD Workstation	749817
HP Z2 G4 CUSTOM WORKSTATION (1HDD)	749585

Ethernet Networking

Description	ITEM NUMBER
8 PORT SWITCH	4140-012-01
ROUTER VPN ETHERNET T50	9963-008
Network Printer	9007-016
CAT5 Ethernet Cable 10Ft.	6400-008

PREVENTIVE MAINTENANCE AND CLEANING

Preventive Maintenance

Preventive maintenance is recommended to be performed on the Surveyor Central System once every 12 months.



Warning: Preventive maintenance is to be performed by Welch Allyn authorized service personnel only. Prior to performing preventive maintenance, be sure the Surveyor Central system is not in active use and all of the clinical data on the system has been properly stored/archived.

Recommended Supplies



- Clean, lint-free cloth
- Cleaning solvent (isopropyl alcohol, 70% pure)
- DRY, low pressure, compressed air (30 psi)
- S4 Patient Monitor
- S4 Battery
- Patient Simulator
- Vacuum cleaner

System / Network Verification

Node to node connectivity check:

From a Surveyor Central control node, communicate to the other nodes of the networked system by opening a command prompt and pinging each node's IP Address per the system network diagram.

This process can also be used for testing communications between the Surveyor Central to S12/S19 Multi Parameter Monitors or S4 mobile monitors. The IP addresses of the S12/S19 must be known to perform this testing, refer to the system networking map for this information.

Note: For this testing it is recommended that all monitoring be suspended.

Export and Archive Function:

Equipment needed: S4 or S12/19 Monitor, patient cable, patient simulator.

- Start a monitoring session on the Surveyor Central using the test transmitter and patient simulator.
- Once the system has had enough time to perform and display measurements on the system display, select 12-Lead+Exp from the Print Option menu.
- Verify the system has exported a digital copy of the ECG to either E-Scribe or the defined export location.
- Verify a hard copy was sent to the defined printer.
- Stop the monitoring session and select the option indicating that the monitoring session just stopped and archive the study from the "Patients" tab.
- Verify the archived data is present in the specified archive path.

Time Synchronization:

- Shutdown all nodes of the Surveyor Central system, except the storage server.
- On the storage server, expand the "Guardian" application.
- Right click anywhere in the guardian application screen and select "Close All" (enter password if prompted).
- Once all Guardian processes close, close the Guardian window.
- Browse to C:\Central\Bin and double click on "BootCentral".
- While the Surveyor Application is booting up, verify that during the bootstrap process it reports "Time Synchronized".

Audible Alarm Testing

Equipment needed: S4 or S12/19 Monitor, patient cable, patient simulator.

Alarm Volume Testing

Select the Configuration Menu and enter a password to proceed. Click on the “Volumes” button and then select “Sound Level”. Note what the sound level is set to, so it can be returned to this setting after the volume testing is completed. Select the different volume options and click on the “Confirm” button to test the audible level of the alarm. Once the levels have been tested, return the level to its original setting.

Alarm Trigger Testing

Admit a patient on the control system for the appropriate channel that you have configured as your test monitor. Verify the “ECG Leads Off” alarm is set to ON for the admitted patient by selecting Alarm Settings, then Technical Alarms. If the “ECG Leads Off” setting is set to OFF, temporarily change the setting to ON to perform this test. Disconnect a lead from the patient simulator and verify that an alarm begins to sound at the appropriate sound level set in the previous step (be sure to reset the alarm control settings to where they were prior to performing this test).

UPS Test / Battery Replacement

UPS equipment no longer provided or supported by Hillrom, responsibility for UPS equipment resides with the customer facility management or IT staff.

System Cleaning

Equipment needed: Vacuum cleaner or compressed air

Open system PCs and remove accumulated dust and debris. Take particular care around cooling fans and inside media access slots. Clean the area the PC(s) and peripheral equipment reside in, to prevent dust and debris accumulation from occurring.

Inspection of PC cooling fans

Inspect CPU fan, and power supply fan. If they are running too slowly or are making any unusual noises during operation, they should be replaced. Improperly operating PC power supply fans require the power supply to be replaced.

Maximizing the Airflow

Keep the system server/s and the workstation/s in an area where the airflow to the front and rear of the system is not obstructed.

If possible, keep the unit off surfaces where dust can gather.

Keep the back of the unit at least 6 inches away from a wall or other obstruction.

Keep the front of the unit clear of any obstruction that keeps air from entering the front of the system.

Remove any dust on the front panel (vent area) and the rear fans with a small vacuum, compressed air, or a clean lint free cloth. It is recommended that this be done on a regular basis (depending on the environment every year, at minimum).

Printer Maintenance and Servicing

Refer to the provided network printer manual for diagnostic testing, error logs, troubleshooting flow chart and prescribed maintenance.

Signal Strength Verification

Network Verification (covered area)

Equipment needed: ECG Simulator, S4 or S12/19 Monitor, and map of covered area.

- Turn on ECG simulator with transmitter and simulator connected.
- Start a Monitoring session
- Verify that the monitor display shows the assigned bed name for the unit and Bed ID entered in the configuration.
- Left click on the bed being monitored and select the **Averages**
- In the upper right of the displayed window locate the signal strength area under the Heart Rate.

If the window below is not present, it must be enabled via the system settings.



S/N (db) -xx/-xxx

- Refer to the original “covered area” map to determine which areas of the facility should display acceptable levels of signal strength.
- Document specific locations on the covered area map by location number (1 thru X) and locate the monitor at these locations while monitoring the signal strength on the Surveyor Central system,

Ensure there are no problems with low signal strength readings, or intermittent signal drop out for the locations defined on the covered area map. Signal strength readings should measure > -75db with an S/N ratio > 20db throughout the entire covered area.

- Document the signal strength readings on the PM report.

Monitor Verification

Turn on the ECG simulator and connect it to one monitor (S4 or S12/19) at a time from location #1 defined in the previous tests. Start a monitoring session on the monitoring slot that matches the Unit, Bed ID (Bed Name) of the transmitter being tested and verify the ECG quality is clean without dropout and has a signal strength > -75db.

Repeat this test for all system monitors.

S12/S19 LAN Connection Verification

This section assumes that the S12/S19 Multi Parameter Monitor have been configured to communicate to the Surveyor Central system via a LAN connection. Please refer to the S12/S19 manuals regarding configuration of the unit.

- Connect the S12/S19 to the Surveyor Central network
- Turn the monitor on
- Connect a simulator to the S12/S19 and verify that waveform is displayed
- Verify that the waveform is displayed on the Surveyor Central display.

Surveyor Central Preventive Maintenance Record

System Serial #: _____

- ☐ System/Network Verification
 - ☐ Verify network connectivity from node to node
 - ☐ Test export and archive functions
 - ☐ Check Time Synchronization
- ☐ Audible Alarm Testing
- ☐ System PC(s) Inspection/Cleaning
- ☐ System Printer(s) - Check if N/A _____
 - ☐ Functional Check
 - ☐ Printer Cleaning
- ☐ Signal Strength Verification (> -75db with an S/N ratio > 20db)
 - ☐ Network Verification (attach covered area map w/locations)

Monitor Location	Signal Strength	Noise level
1		
2		
3		
4		
5		
6		

- ☐ Monitor Verification (S4, S12, S19)

Performed By: _____ Date: ____/____/____

PC Repair – HP Model Z2

Before You Begin

1. Use an electrostatic discharge (ESD) wrist strap to avoid damaging any circuitry.
2. Remove all devices (such as diskettes and CD-ROMs) from the computer.
3. Power off the computer and any peripheral devices that are connected to it.



Warning:

Be sure the AC power cord is disconnected prior to performing servicing.

4. Disconnect the power cord from the electrical outlet and then from the computer. When the computer is plugged into an AC power source, there is always voltage applied to the system board. You must disconnect the power cord from the power source before opening the computer to prevent system board or component damage.
5. Disconnect all peripheral device cables from the computer.

Static Electricity

Static electricity can damage electrical components. Before removing or replacing a component, utilize static protection equipment, or physically contact a grounded metal object to discharge static electricity. Also observe the following precautions to prevent damage to electric components and accessories:

- To avoid hand contact, transport products in static-safe containers such as tubes, bags, or boxes.
- Protect all electrostatic parts and assemblies with conductive or approved containers or packaging.
- Keep electrostatic-sensitive parts in their containers until they arrive at static-free stations.
- Place items on a grounded surface before removing them from their container.
- Always be properly grounded when touching a sensitive component or assembly.
- Avoid contact with pins, leads, or circuitry.
- Place reusable electrostatic-sensitive parts from assemblies in protective packaging or conductive foam.

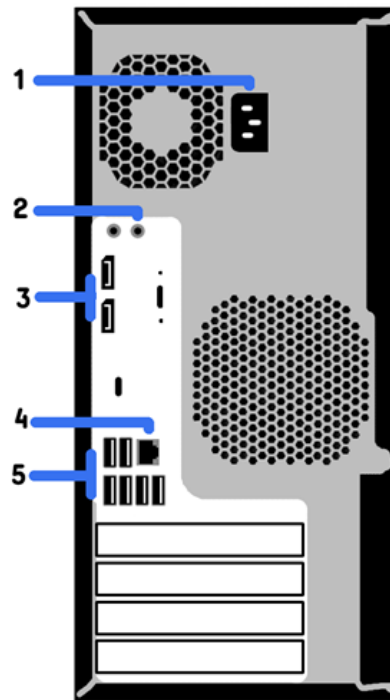
Disassembly

- During disassembly, label each cable as you remove it, noting its position and routing, or take a photo of the cable positions and routing before and/or during the disassembly process. This will make the replacement of the cables much easier, and will ensure that the cables are rerouted properly to protect the cables.
- Keep all screws with the device it was removed from. The screws used in the computer may be of different thread sizes and length; installing screws incorrectly could damage the device.

HP Model Z2 PC



Figure 1 - Z2 Tower Diagram



Overview

- 1 – Power cord socket
- 2 – Audio line out
- 3 – DisplayPort output
- 4 – Network port
- 5 – USB ports

Required Tooling:

- Phillips #2 Screwdriver
- Torx 15 Screwdriver
- Flat-bladed screwdriver (may sometimes be used in place of T15 driver)

Access Panel Removal



Warning:

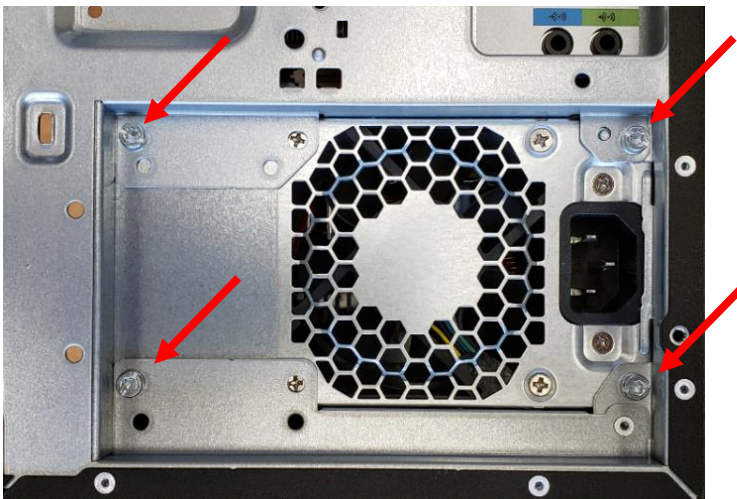
Be sure the AC power cord is disconnected prior to performing servicing.

Lift latch handle to
remove side cover.



Power Supply Replacement

- Prepare the computer for disassembly.
- Remove the access panel.
- Remove the 4 mounting screws shown below.



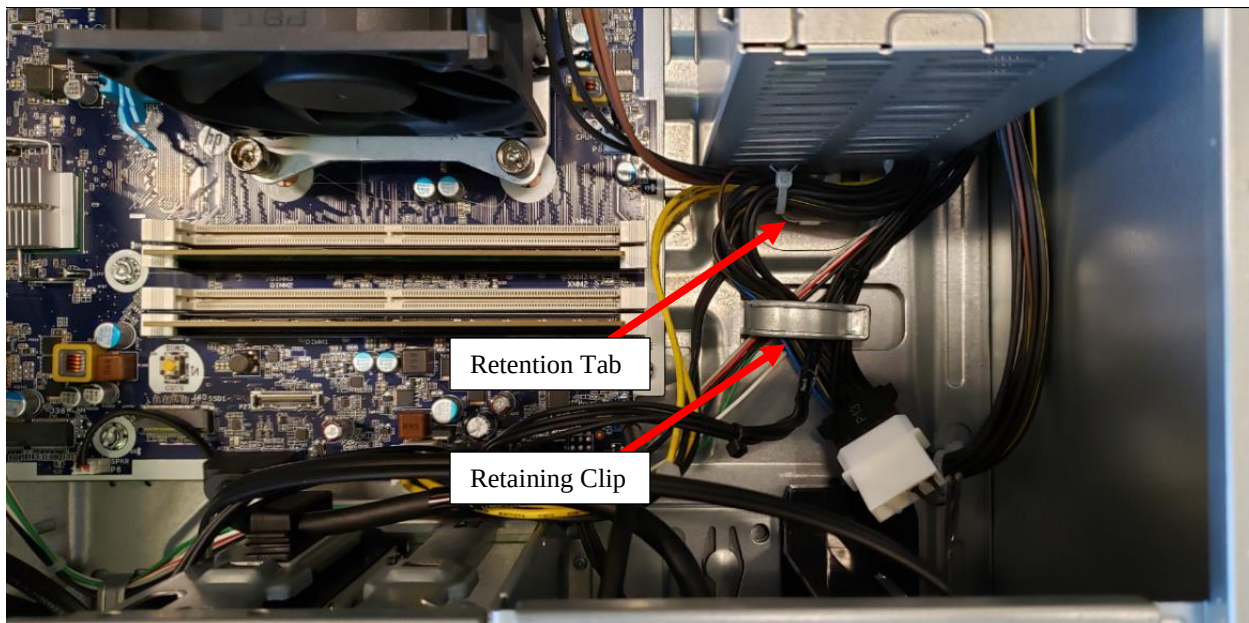


Caution: Static electricity can damage electrical components.

Disconnect the power supply interconnect cables (DVD Drive, motherboard, hard drive), and slide them out of the retaining clip used to position the wires.

Once completed, remove the Power Supply from the PC by depressing the retention tab on the chassis to allow the power supply to slide out of its mounted position.

Reinstall in reverse order.



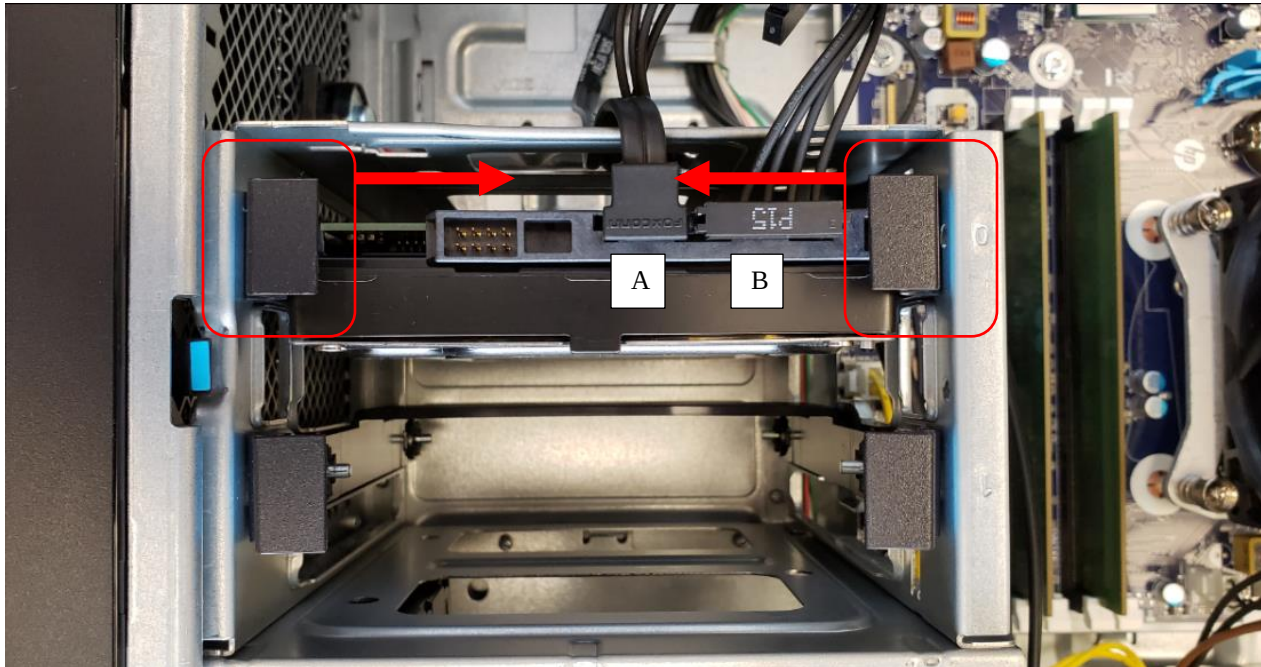
Hard Drive Replacement

Based on the type of node, one or two hard drives may be present.



Caution: Static electricity can damage electrical components.

- Prepare the computer for disassembly
- Remove the access panel
- Disconnect the data and power cables from the hard drive (labeled A and B below respectively).
- Squeeze the retaining clips gently together to allow the hard drive to slide out of the drive rack.



The drive rails will need to be removed and mounted to the new drive prior to installation by flexing the plastic rail material to allow the mounting pins to exit the drive holes.



Once the rails are in place, slide the new drive into the drive rack, and reinstall the data and power cables.

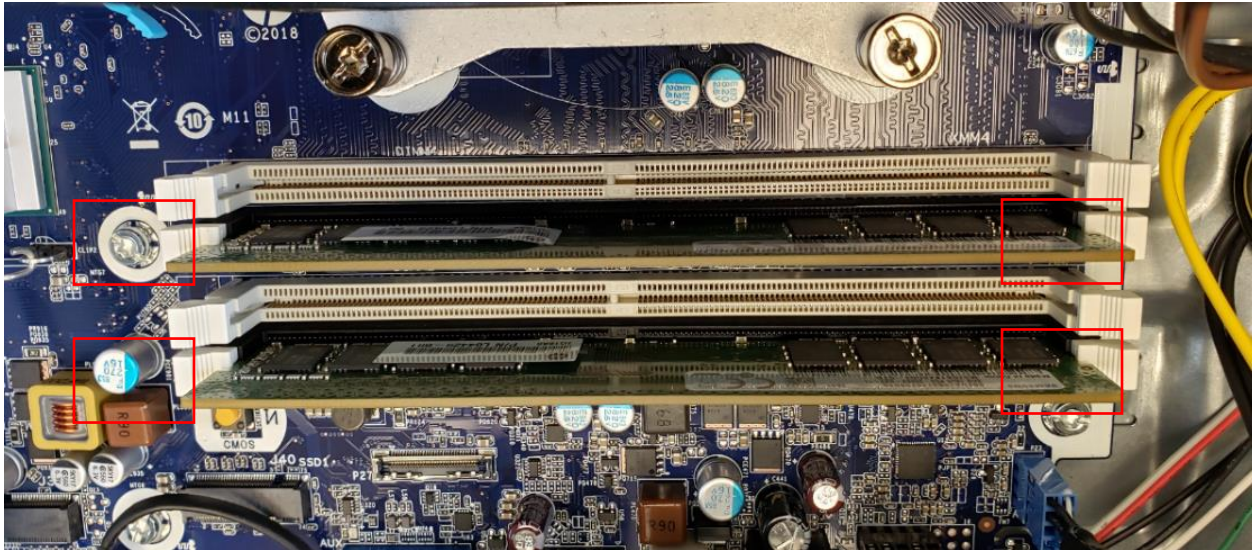
RAM (Random Access Memory) Replacement



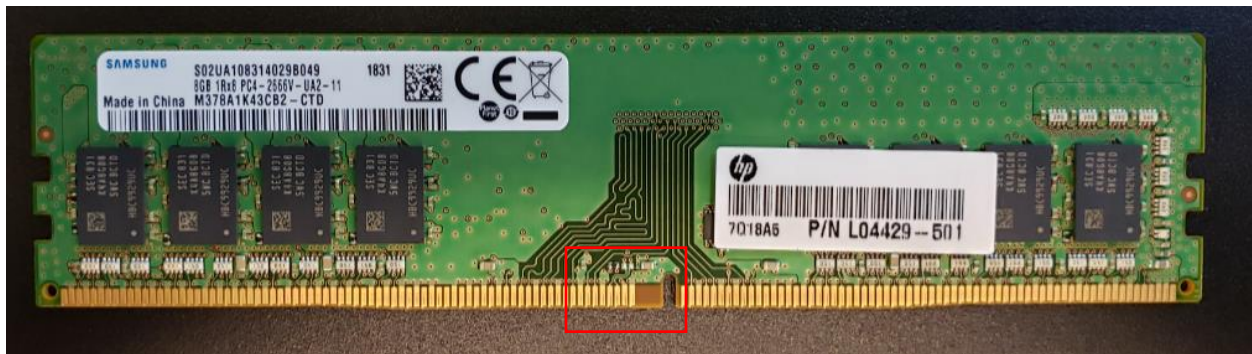
Caution: Static electricity can damage electrical components.

To replace the RAM

- 1) Push down and out on the side tabs for the RAM module to be removed.



- 2) Take note of the notch on the RAM stick (offset from center) when installing replacement RAM.



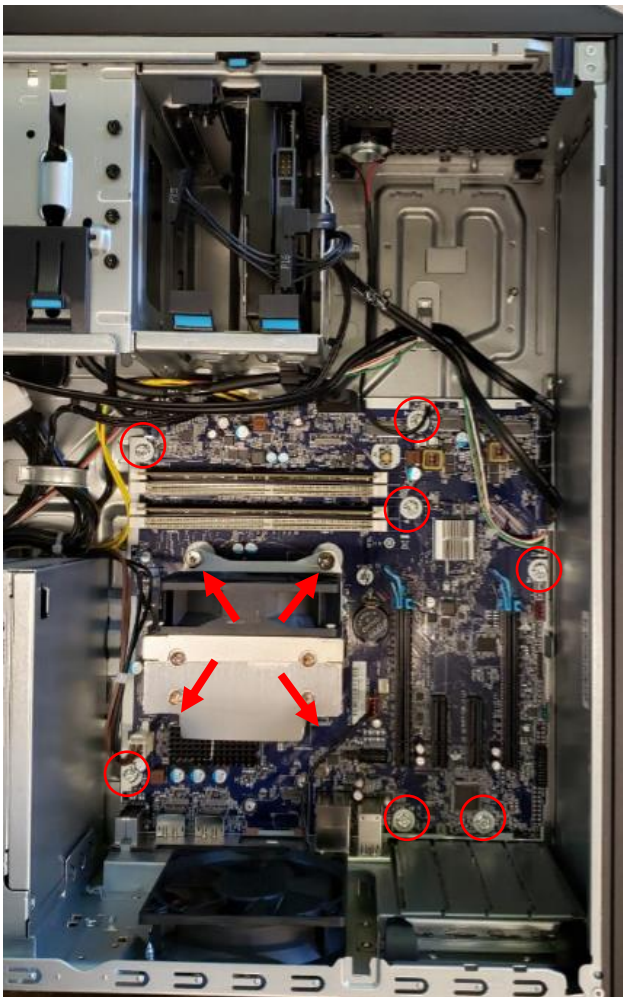
- 3) Install the replacement RAM into the notched RAM slot and push down on the sides of the RAM to lock into place. The latching tabs should move into a vertical position to hold the RAM into place firmly.

Motherboard Replacement



Caution: Static electricity can damage electrical components.

- Prepare the computer for disassembly
- Remove the access panel
- Disconnect all cables and storage devices from the PC motherboard.
- Remove the 7 mounting screws with a T15 Torx or straight blade screwdriver.
- Loosen the 4 retention screws attached to the CPU cooler that are also connected to the PC chassis.



Zoom View of data cable connections



NOTE: When replacing the system board, be sure that the CPU cooler and system memory are removed from the defective motherboard and installed on the replacement motherboard.

Remove the CPU cooler and set it aside to be used when installing the new motherboard.



Remove the motherboard from the chassis.



Install the new motherboard by angling the board into the chassis with the external connectors being lowest point as it is placed onto the chassis mounts.

Reassemble in reverse order.

TROUBLESHOOTING

Surveyor Central 5.x.x

1. . Error Logs:

The LogHound utility will retrieve all of the necessary log files from each node in the system, and package them into a single file for easy access and transmission for service use.

To collect the system log files for troubleshooting purposes, follow the instructions below.

1. On any Surveyor station press Ctrl+Shift+Esc to open Task manager
 2. Click File > Run New Task > Type in EXPLORER
 2. Navigate to C:\Setup\Tools and click on the **Log_Hound.bat** file
 3. After the batch file has complete the collection of the necessary files, go to c:\LogHoundTmp to copy the 7-Zip file for transfer to Technical Support personnel.
- Each individual Surveyor System PC has it's own error logs. The error logs are located in C:\Central\Logs and they are date stamped with Debug.log being the most present copy
 - Once error logs are retrieved from the location mentioned above, look through the correct error log at the time the error occurred. These files are a very important part in Welch Allyn technical support's troubleshooting effort.
 - Example Error Logs:

The example listed below displays an issue with the time being out of sync:

```
<11>Jan 7 08:23:21.843 192.168.10.111 SCV1T1 1332 timeman.exe 1900 E timeapp.cpp 467
TimeApp::timesync_loop Time overflow: Server Time '01/07/2009 14:22:24' (utc), Diff (srv-self) -
56875, limit 200 ms
<13>Jan 7 08:23:24.483 192.168.10.111 SCV1T1 1352 soundman.exe 280 M medapp.cpp 985
MedicalApplication::set_running Bed (1,0) status: RUNNING
<13>Jan 7 08:23:24.483 192.168.10.111 SCV1T1 1332 timeman.exe 1900 M medapp.cpp 985
MedicalApplication::set_running Bed (1,0) status: RUNNING
<13>Jan 7 08:23:24.514 192.168.10.111 SCV1T1 1380 centralview.exe 1384 M medapp.cpp 985
MedicalApplication::set_running Bed (1,0) status: RUNNING
<13>Jan 7 08:23:24.514 192.168.10.111 SCV1T1 1380 centralview.exe 1384 M centralbed.cpp 52
CentralBed::set_status MONITOR_RUNNING_BLIND
<13>Jan 7 08:23:24.577 192.168.10.111 SCV1T1 1380 centralview.exe 1384 M centralbed.cpp 52
CentralBed::set_status MONITOR_RUNNING_BLIND
<12>Jan 7 08:23:25.467 192.168.10.111 SCV1T1 1380 centralview.exe 1384 W mainscreen.cpp 466
TFormMain::cmd_ack_timeout_handle Cmd CMD_START_SESSION to: REPEATER not
acknowledged
<11>Jan 7 08:23:31.997 192.168.10.111 SCV1T1 1332 timeman.exe 1900 E timeapp.cpp 467
TimeApp::timesync_loop Time overflow: Server Time '01/07/2009 14:22:35' (utc), Diff (srv-self) -
56872, limit 200 ms
```

```
<11>Jan 7 08:23:42.150 192.168.10.111 SCV1T1 1332 timeman.exe 1900 E timeapp.cpp 467
TimeApp::timesync_loop Time overflow: Server Time '01/07/2009 14:22:45' (utc), Diff (srv-self) -
56868, limit 200 ms
```

The error logs will provide the date, time, IP address of the PC the logs were extracted from, Computer name, error identifier number, the process that generated the message, and the status of the message. Once the error logs are extracted, searching for key words such as: crash, restart, etc. will help in finding the cause of the error.

If further investigation is needed, email a copy of the error logs to Welch Allyn Tech Support with a brief description of the problem with the time and date that this error occurred.

2. If Printouts seen with the following errors:

- ? = The generating process is not able to generate the parameter because of technical problems.
- ?? = The parameter is expected but has not been received.
- ??? = The received parameter is outside a valid range, or has been marked "invalid" by the generating process.
- = Parameter is disabled by the generating process.

Possible solutions:

- Check to see that the transmitter is not out of range and is functional
- The parameter may be outside of a valid clinical range
- The parameter is disabled by the generating process (e.g. monitoring stopped or cardiac arrest)
- Try selecting a different time point and reprint needed printout
- Possible system error – Contact Welch Allyn Technical Support

3. Telemetry Central does not print:

Possible solutions:

- Printman.exe not running on the storage system. If Printman is not running restart task in guardian, located on the storage node by right clicking on the Guardian screen, then select Start Application, and double click on Printman.
- Printer malfunction, troubleshoot printer, i.e, does printer print test page?
- If the printer is able to print a test page, verify the printer has the correct IP address assigned to the printer. The IP address is accessed in the printer by pressing the **MENU** button, use the up down arrow keys to highlight the desired option, select **CONFIGURE DEVICE, I/O, EMBEDDED JET DIRECT, TCP/IP, MANUAL SETTINGS, IP ADDRESS**. If the IP address is not correct, make changes to correct the address.
- Verify the printer, and all nodes are properly connected to a switch/router and power is connected to the switch and router. If the network cable is properly connected to the printer and the switch you will see an indicator light 'on' near the network cable connection.
- Verify IP Address is correctly installed in the System and the printer. To do this, Select Printer and Faxes in the Control Panel. Next right click on the printer and select properties. Inside of the properties selection, navigate to the Port tab and verify IP address located here matches the IP of the printer. Once verified navigate to a command prompt on the node and attempt to PING the printer to confirm the connection.

Local troubleshooting should be performed using the supplied manual and its 'Problem Solving' and 'Troubleshooting Flow Diagrams'. More information on the HP M608n printer (or the previous model HP4250) can be found in the product manuals on the internet.

4. Control Station displays “Storage Disabled”:

Possible solutions:

- Verify that Storage Node is on
- If Storage node is on, check the processes running on storage node and make sure Storeman.exe is still running. If not, restart the process by right clicking on the Guardian screen and select Start application and then double click on Storeman
- If “Storage Disabled” is only displaying on certain monitoring slots and the data can be reviewed, this is a false message. The data is properly storing and only displaying the message because the sending process is not being properly acknowledged.
- Possible faulty connection of view station to Storage Node. Check connections to all computers, and switches. Network cable to storage server should go to the standard network port, and not the port labeled iLO

After checking all of the above and the Storage function is still not working properly:
Contact Welch Allyn service department for assistance.

5. Watchdog Alarms:

- **“Odd” sound heard every few minutes:**

Possible solutions:

- Unit has the alarms disabled

Note: When alarms are disabled no alarms will sound, this includes the arrest alarm, be careful when choosing to disable alarms. The customer assumes all risks for turning off alarms.

4. Rapid beeping tone emitted from system:

Possible solutions:

1. Verify that there is power to the watchdog unit located on the side of the control station
2. Check to make sure that all Guardian processes are running and has a green indication light next to it. If it has a red or orange indication dot by it, close and then restart that process

5. Rapid beeping tone emitted from system along with high pitched tone:

Possible solution:

1. Check the USB cable connection between the watchdog and the control station.

6. Can not assign patient, review patient, perform resting interpretation:

Possible solution:

- Verify all Guardian processes are running and has the green indication light, if there is a red light by one of the processes, restart that process
- Possible problem with Time synchronization, refer to section below

- Incorrect IP address prevents these processes from running, contact Welch Allyn service department for assistance.
- In the case of S12 and S19 Patient monitors verify that the IP address is correct and that the Bed ID and Unit ID are set correctly.

7. No waveforms displayed, problems with printing, storage, and review:

Possible solution:

- Possible problem with the time synchronization.
- Try to close and then restart Timeman.exe. To close Timeman.exe, access the Task Manager by pressing Ctrl+Shift+Esc Next, expand the Guardian application and right click on Timeman process. Then select "Close Process" and right click again and select "Start Application" and double click on Timeman. This will restart the Timeman application and resynchronize the time service.

8. Analysis, Full Disclosure, and Clinical Options not working:

Possible solution:

- Verify system has this feature enabled by Welch Allyn
- Possibly the hash key has been changed. If this is changed all options are disabled, contact Welch Allyn service department for assistance.

9. Forgotten Password:

Possible solutions:

- Try typing 'mortara' (all lower case) as the password, if this does not work, contact Welch Allyn service department for assistance, to reset password.

10. No Telemetry signal present, symptom related to only 1 patient window:

- **Square waves on display for 1 patient only.**

Possible solutions:

1. Make sure transmitter is turned on and configured to the correct Unit and Bed ID.
2. Verify the S4 transmitter is connected to Wireless network
 - i. If unable to connect to wireless network:
 - a. Verify network settings on device are configured properly per facility wireless network specifications (IPv4 settings, SSID, password)
3. If connected to wireless network, but S4 transmitter displays trying to connect to central:
 - a. Verify Unit and Bed ID are configured properly
 - b. Verify Host IP is configured correctly
 - c. Verify all S4Tconnector processes are running in the Guardian window of the control node associated to the Unit ID assigned to the affected bed
4. If possible try another known good transmitter configured to the Unit and Bed ID of the affected window to narrow it down to what is causing the problem. If the signal shows after the transmitter swap, then it is a defective transmitter.

11. No Telemetry signal present, symptom related to all windows:

Possible solutions:

- Verify that all S4Tconnector processes are running on in the guardian window of all control nodes
- Verify WatchGuard firewall is powered on and link is established on both active interfaces

12. Network Reception:

• **Bad Coverage in 1 area:**

Possible solutions:

This symptom can be caused by several failures.

- Verify AP in this specific area is on line
- Verify AP is broadcasting the dedicated SSID on the 2.4 GHz Bandwidth
- Verify S4 signal strength (>-75 db) and Signal to noise Ratio (>20 db) is within specs

13. IT Network:

From the storage node: Verify that ping is successful to all nodes on the system as well as the S4 transmitters

If a packet loss occurs, there is a network issue.

• **Fast Ethernet Switch Troubleshooting**

Possible Solution:

- If there is a problem with the switch, power cycle switch to restore connections
- If the Power LED or indicator is OFF:
 1. Ensure the power cord is secure at both ends, and is not damaged.
 2. Verify that the outlet has power.
 3. Verify the cable is not damaged, pinched or frayed. Replace if this is the case.
 4. Try using another power cord that is of an identical type.

• **LINK or Activity LED is OFF**

- The LINK LED is usually OFF when the device at the other end of the CAT 5/5e/6 cable is OFF, disconnected, the cable is faulty, or the connector has oxidized and requires cleaning. The LINK LED at the switch, is illuminated when there is another device attached via a CAT 5/5e/6 cable.
 1. Make sure the network cable connections are clean and properly connected.
 2. Make sure both devices attached to the network cable are powered on.
 3. The network cable is faulty. This may be apparent after checking the cable connections, or, if the LEDs on the end-node devices are both OFF.
 4. The CAT 5/5e/6 maximum cable length must not exceed 100 meters or 328 feet. If the network cable exceeds 328 feet, performance may be diminished.
 5. The devices attached to the cable, must be configured identically for 10 Mbps or 100 Mbps.

14. VPN Router setup:

Possible Solution:

- If any of the features below are not working correctly, the router may be the cause.
 1. Unable to export to Unipro server.
 2. Unable to Archive study data.
 3. Unable to store 12 lead ECG's on the E-Scribe.
 4. Time on Central System not in sync with the external time server.

Please contact Welch Allyn Tech Support for assistance.

15. Power Up and Power Down Procedure:

- **To Power down Surveyor Central Telemetry System proceed as follow:**
 1. First, power off the Control Nodes (SCV1 & SCV2) normally located in Nurses Station:
 - Stop monitoring of all patients.
 - Select the **Config** tab at the bottom right hand corner of the screen.
 - Password is **mortara or Facility's password**.
 - Select **Shutdown Computer**.
 2. The last step in shutting down the Surveyor Telemetry Central is to shut down the Storage Node (SCS1) also located in IT Closet:
 - Expand **Guardian**.
 - Right click on Guardian window and a pop up asking for the password will appear, password is **mortara**, and select **Shutdown System**.
- **To Power On Surveyor Telemetry Central System proceed as follow:**
 1. Power on the system in the following order **Storage Node (SCS1)**, then the **Control Nodes (SCV1 & SCV2)**.

Note: Powering off and on of the Surveyor Telemetry Central system has to be done in the exact orders as stated above. Failure to follow instructions will cause unwanted problems. Disregard the procedure if your Surveyor Telemetry Central System is a stand-a-lone system.

16. Repeater Standalone not working:

- **No Tracings seen on screen:**

Check IP address:

1. Right click on Repeater shortcut Icon and select Properties
2. In the Shortcut Tab, verify the Target line lists the correct IP
3. Verify that all processes running on Guardian has a green dot next to them
4. Check rules in the security router

Verify the channels are selected:

1. Click on CONFIG and enter password.
2. In the bed list make sure the beds you want are checked and view leads are selected.

17. Review Standalone not working:

- Verify all network cables are connected
- Verify IP address is correct
- Verify that all processes running on Guardian has a green dot next to them
- Verify dongle has correct permissions
- Check that the correct Data Source Type is selected
- Verify location of Data Source Type is correct
- Check rules in the security router
- If viewing Online Database, verify the IP address is correct, and user permissions have been entered into the configuration screen of Surveyor Central.

18. No Plethysmograph tracing is displayed:**Remove references to T12 and v4**

- Verify that Surveyor Telemetry System has software version 4.3.0 or newer (previous versions not compatible).
- In the Config menu, verify that the transmitter type in the Monitor Kind field is set to S4 SP02.
- Verify that the transmitter used is a S4 with SP02
- Check SpO2 sensor finger clip/wrap and verify that the sensor indicator light is on
- Make sure that the Plethysmograph is selected in the Settings menu, under Display and 12-Lead. The system can only display 12 tracings total. Therefore, in order to display the plethysmograph, one of the other lead tracing will have to be unchecked and the plethysmograph selected

Conformance Testing

Conformance testing is to be performed by Authorized Service Representatives to verify the device is functioning correctly after repair operations have been performed. Testing results should be documented on the test data record at the end of this section of the manual.

Due to the complexity of the Surveyor Central System, not all sections of the conformance testing procedure may be required to verify conformance of a particular repair activity. Based upon the repair performed, the repair technician may deem various sections as “non-applicable” since they were not related to the functions associated with the repair; in such cases the decision to exclude a section shall be documented on the test data record provided.

System/Network Verification

Node to node connectivity check:

From a Surveyor Central control node, communicate to the other nodes of the networked system by opening a command prompt and pinging each node’s IP Address per the system network diagram.

This process can also be used for testing communications between the Surveyor Central to S12/S19 Multi Parameter Monitors. The IP addresses of the S12/S19 must be known to perform this testing, refer to the system networking map for this information.

Note: For this testing it is recommended that all monitoring be suspended.

Export and Archive Function:

Equipment needed: S4 or S12/19 Monitor, patient cable, patient simulator.

- Start a monitoring session on the Surveyor Central using the test transmitter and patient simulator.
- Once the system has had enough time to perform and display measurements on the system display, select 12-Lead+Exp from the Print Option menu.
- Verify the system has exported a digital copy of the ECG to either E-Scribe or the defined export location.
- Verify a hard copy was sent to the defined printer.
- Stop the monitoring session and select the option indicating that the monitoring session just stopped and archive the study from the “Patients” tab.
- Verify the archived data is present in the specified archive path.

Time Synchronization:

- Shutdown all nodes of the Surveyor Central system, except the storage server.
- On the storage server, expand the “Gaurdian” application.
- Right click anywhere in the guardian application screen and select “Close All”.
- Once all processes are closed, Close the Guardian Window.
- Browse to C:\Central\Bin and double click on BootCentral.
- Once the Surveyor Application is booting up, verify that during the bootstrap process it states “Time Synchronized”.

Audible Alarm Testing

Equipment needed: S4 or S12/19 monitor, patient cable, patient simulator.

Alarm Volume Testing

Select the Configuration Menu and enter a password to proceed. Click on the “Volumes” button and then select “Sound Level”. Note what the sound level is set to, so it can be returned to this setting after the volume testing is completed. Select the different volume options and click on the “Confirm” button to test the audible level of the alarm. Once the levels have been tested, return the level to its original setting.

Alarm Trigger Testing

Admit a patient on the control system for the appropriate channel that you have configured as your test monitor. Verify the “ECG Leads Off” alarm is set to ON for the admitted patient by selecting Alarm Settings, then Technical Alarms. If the setting is set to OFF, temporarily change the setting to ON to perform this test. Disconnect a lead from the patient simulator and verify that an alarm begins to sound at the appropriate sound level set in the previous step (be sure to reset the alarm control settings to where they were prior to performing this test).

UPS (Uninterruptable Power Supply)

UPS equipment no longer provided or supported by Hillrom, responsibility for UPS equipment resides with the customer facility management or IT staff.

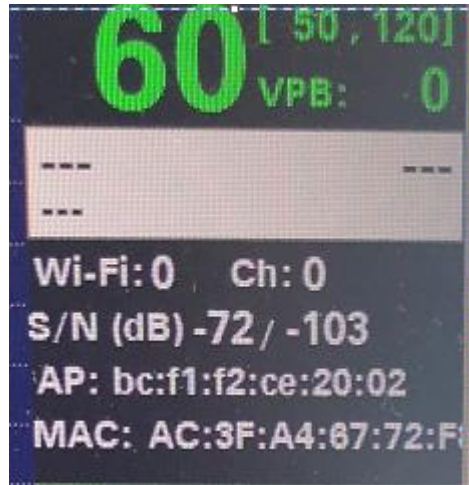
Network Verification (covered area)

Equipment needed: ECG Simulator, S4 or S12/19 Monitor, and map of covered area.

- Turn on ECG simulator with transmitter and simulator connected.
- Start a Monitoring session
- Verify that the monitor display shows the assigned bed name for the unit and Bed ID entered in the configuration.
- Left click on the bed being monitored and select the **Averages**

- In the upper right of the displayed window locate the signal strength area under the Heart Rate.

If the window below is not present, it must be enabled via the system settings.



S/N (db) -xx/-xxx

- Refer to the original “covered area” map to determine which areas of the facility should display acceptable levels of signal strength.
- Document specific locations on the covered area map by location number (1 thru X) and locate the transmitter at these locations while monitoring the signal strength on the Surveyor Central system,
- Ensure there are no problems with low signal strength readings, or intermittent signal drop out for the locations defined on the covered area map. Signal strength readings should measure >-75db throughout the entire covered area.
- Document the signal strength readings on the test data record.

System Printer(s)

Refer to the provided network printer manual for diagnostic testing, error logs, troubleshooting flow chart and prescribed maintenance.

Monitor Verification

Turn on the ECG simulator and connect it to one monitor (S4 or S12/19) at a time from location #1 defined in the previous tests. Start a monitoring session on the monitoring slot that matches the Unit, Bed ID (Bed Name) of the transmitter being tested and verify the ECG quality is clean without dropout and has a signal strength > -75db.

Repeat this test for all system monitors.

S12/S19 LAN Connection Verification

This section assumes that the S12/S19 Multi Parameter Monitor have been configured to communicate to the Surveyor Central system via a LAN connection. Please refer to the S12/S19 manuals regarding configuration of the unit.

- Connect the S12/S19 to the Surveyor Central network
- Turn the monitor on
- Connect a simulator to the S12/S19 and verify that waveform is displayed
- Verify that the waveform is displayed on the Surveyor Central display.

Surveyor Central Conformance Test Record

System Serial #: _____

System/Network Verification _____ Pass/Fail/NA

Verify network connectivity from node to node
Test export and archive functions
Check Time Synchronization (where applicable)

Audible Alarm Testing _____ Pass/Fail/NA

Network Verification (> -75db with an S/N ratio > 20db) _____ Pass/Fail/NA

(attach covered area map w/locations)

Transmitter Location	Signal Strength	Noise level
1		
2		
3		
4		
5		
6		

System Printer(s) _____ Pass/Fail/NA

- ☐ Functional Check
- ☐ Printer Cleaning

System Monitors _____ Pass/Fail/NA

S12/S19 Patient Monitors (LAN) _____ Pass/Fail/NA

Performed by: _____ Date: ____/____/____

SYSTEM SPECIFICATIONS

Applied standards

Workstations, printer, monitor

UL-listed, Comply with FCC part 15, class B,

CE-labeled according to EU directives 73/23 (Low Voltage) and 89/336 (Electromagnetic Compatibility)

System

IEC 60601-1:2005 Ed:3 Medical electrical equipment Part 1: General requirements for basic safety and essential performance

European Union: CENELEC EN60601-1:2006 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance

USA: AAMI ES60601-1:2005 Medical electrical equipment Part 1: General Requirements for Basic Safety and Essential Performance

Canada: CSA C22.2#60601-1:2008 Ed:3 Medical Electrical Equipment – Part 1: General requirements for basic Safety and essential performance

IEC 60601-1-8:2012-1 Edition 2.1, Medical Electrical Equipment – Part 1-8: General Requirements for Safety and Essential Performance – Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-2-49 Edition 2.0: 2011, Medical Electrical Equipment, Part 2-49: Particular requirements for the safety of multi-function monitoring equipment (only applicable items relating to distributed alarm systems)

IEC 60601-2-25:2011-10 Edition 2.0, Medical Electrical Equipment. Part 2-25: Particular requirements for the basic safety and essential requirements of electrocardiographs.

IEC 60601-2-27:2011 Ed:3 Medical Electrical Equipment PT. 2: Particular Requirements for the Safety, including essential performance, of Electrocardiographic Monitoring Equipment

ANSI/AAMI EC57:2012 -- Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms

ANSI/AAMI EC38:1998 (only applicable items relating to ST monitoring and reporting)

Council Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

Part 11 of Title 21 of the USA Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11). (applicable only where electronic records such as 12-lead resting ECG's are produced).

ISO 9919:2005, Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (2nd Edition). – (only relates to T12S transmitter)

IEC/EN 62304:2006+AC:2008 - Medical device software - Software life-cycle processes).

IEC 60601-1-6:2010-01 Edition 3.0, Medical Electrical Equipment – Part 1-6: General Requirements for Safety and Essential Performance – Collateral Standard: Usability. and IEC 62366:2007- Medical devices - Application of usability engineering to medical devices

EN 980:2008 Symbols for use in the labeling of medical devices

EN 1041:1998 Information supplied by the manufacturer of medical devices

Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”) as defined per Health Insurance Portability and Accountability Act (“HIPAA”) of 1996 (amended through August 2002) per the United States 45 CFR Part 160 and Subparts A and E of Part 164,

IEC 80001-1 Edition 1.0 2010-10 Application of risk management for IT networks incorporating medical devices

Part 1: Roles, responsibilities and activities.

Part 2-1: Step-by-step risk management of medical IT networks—Practical applications and examples.

Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls.

Part 2-3: Guidance for wireless networks.

Specifications

System

Mode of Operation	Continuous
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ECG

NOTE: Refer to the Surveyor S12/S19 patient monitor user manual, part number 9515-183-51-ENG, for the specification of its parameters communicated to and managed by the Surveyor Central including associated ranges and accuracy.

ECG acquisition:	10-wire (12-lead): I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 5-wire (7-lead): I, II, III, aVR, aVL, aVF, V 3-wire (1-lead): I, II or III
Acquisition:	40,000 s/s (Surveyor S4) for pacemaker detection, reduced to 500 samples/s
Resolution:	2.5 μ V.
Dynamic range/offset tolerance:	$\pm$ 340 mV
Input dynamic:	680 mV
Common Mode Rejection Ratio:	100 dB, up to 180 dB with digital filter at 50 or 60 Hz (ANSI/AAMI EC 13)
Frequency response:	Diagnostic ECG-standard IEC 60601-2-25 and ECG monitoring standard IEC 60601-2-27
Input impedance:	200 M Ω (Surveyor S4)
Defibrillator protection:	Only when used with Welch Allyn ECG cables
Beat detection:	Sensitivity 99.90%, positive predictivity 99.88% (AHA/MIT database)
Beat recognition:	Normal, ventricular, paced, unknown

Heart rate measurement:	Range: 30-300 bpm; Resolution: 1 bpm Measurement error (RMS) as measured according to ANSI/AAMI EC57: 2.8% AHA database, 1.7% MIT database
HR Averaging	If the heart rate from the last four R to R intervals is greater than 48 beats per minute, the average heart rate is determined by averaging the last 16 R to R intervals. If the heart rate from the last four R to R intervals is less than or equal to 48 beats per minute, then this rate is used. Paced beats and PVCs are included in the heart rate calculation.
ST level measurement:	Range: -2500 to +2500 μ V (-25 to +25 mm) Resolution: 10 μ V (0.1 mm) Measurement error: Mean 8.5 μ V, Standard Deviation 66 μ V as measured according to ANSI/AAMI EC57 on the ESC-ST database

NOTE: For SpO₂ specifications of the Surveyor S4, refer to the Surveyor S4 User Manual, p/n 9515-190-51.

Alarms

Number Alarms level:	4 (high, medium, low, and information only)
Visual alarm presentation:	Color-coded text message by priority (red, yellow, cyan, white) Blinking, for active alarm Stationary when alarm condition still present but silenced by operator
Audible alarm sound pressure level:	External USB connected speaker 5 volume settings SPL ranges (measured according to IEC 60601-1-8 :2012): USB Speaker Logitech S-150: : High priority alarms: 58.44dBA to 68.01 dBA Medium priority alarms: 60.41 dBA to 65.58 dBA

Alarms groups

Electrocardiogram:	Arrest:.....High priority, limits 2-8 seconds VFIB:.....High priority
Heart Rate:	Bradycardia: High/Medium/Low priority, low HR – 10 bpm Low Heart Rate: Medium priority, limit 20-100 bpm High heart rate: Medium priority, limit 50-250 bpm Tachycardia: High/Medium/Low priority, high heart rate + 30 bpm
Ventricular Tachycardia:	VTACH: High priority, 3 – 20 beat run length (user selectable), 100 – 200 beats/min (user selectable) Sustained VTACH:....High priority, > 15 second duration
ST Change:	ST Increase: Medium/Low priority ST Decrease:.....Medium/Low priority User-selectable limits 100-900 μ V (1 – 9 mm) change User-selectable ST delay, post J-point (10-200 ms)
Extended Arrhythmias for telemetry patient monitoring:	Medium, low/On or Off (user selectable) Trigeminy, Bigeminy, High Ectopic Rate, R-on-T Rate, High R-on-T Rate, Multifocal Ectopics, Couplet, High Couplet Rate, Ventricular Run, Ventricular Rhythm, Dominant Rhythm Change, Missing QRS, High Pause Rate, Irregular Rhythm, Low QRS Voltage, Pacemaker Output Failure, High Output Failure Rate, Pacemaker Non-Capture, High Non-Capture Rate
Extended Arrhythmias for S12/S19 patient monitoring:	Medium, low, or information only/On or Off (user selectable) Ventricular Run, Ventricular Rhythm, Couplet, High Ectopic Rate, Bigeminy, Missing QRS, Irregular Rhythm, Pacemaker Non-Capture
Resting ECG for telemetry monitoring: (optional - requires 12-lead Interpretation)	Low or information only priority/On or Off (user selectable) QTc High:.....300-600 ms QTc-Bazett High: 300-600 ms QTc-Fridericia High: 300-600 ms

Telemetry SpO ₂ : (optional - requires T12S)	Medium/On or Off (user selectable) SpO ₂ Low: Medium priority, 50-98% saturation Desaturation:.....High priority, 10% below SpO ₂ low limit Pulse rate low: Medium or Low priority, 20-100 pulse rate Pulse rate high: Medium or Low priority, 50-250 pulse rate
Technical Alarms – General	Printer error (low priority) No AC Power (low priority) Printer off-line (low priority) Storage space < 24hr (low priority) Deleting old sessions (low priority) Hard disk full (low priority) Storage system unreachable (low priority) Repairing database (low priority)
Technical Alarms for telemetry	ECG Lead Off (low/information only priority) ECG Noise (low/information only priority) Patient Call (medium/low/information only priority) No Radio Signal (low/information only priority) Radio Interference (low/information only priority) Battery Low (information only) Electrode impedance test(information only) 12-lead ECG taken(information only) Synchronizing clocks(information only) System battery power low (information only) No Heart rate (medium priority) ECG monitoring disabled (medium priority) Alarm engine fault (medium priority)

Technical Alarms for patient monitoring	Network Connection Lost (low priority) SpO2 Hardware Failure (low priority) SpO2 Unplugged (low priority) SpO2 Artifact (low priority) NIBP Artifact (low priority) NIBP Blocked Line (medium priority) NIBP Open Line (low priority) NIBP Timeout on Measurement (low priority) NIBP Measurement Failure (low priority) Temperature Unplugged (low priority) Temperature Too High (low priority) Temperature Hardware Failure (low priority) Respiration Leads Off (low priority) Respiration Artifact (low priority) Respiration Too High (low priority) CO2 Hardware Failure (low priority) CO2 Unplugged (low priority) CO2 Occluded Line (low priority) CO2 Too High (low priority) FICO2 Too High (low priority) Pressure Unplugged (low priority) Pressure Hardware Failure (low priority) Pressure Needs Calibration (low priority) Pressure Needs Zero (low priority) Pressure Artifact (low priority) Pressure Too Low (low priority) Pressure Pulse Rate Too Low (low priority) Pressure Too High (low priority) Pressure Weak Signal (low priority) Arrhythmia Disabled (low priority) Check Leads (low priority) Heart Rate Artifact (low priority) Monitor Low Battery (low priority) Art Line Open (high priority)
Protocol events: (optional)	Information only: Protocol completed, Protocol aborted Medium, low or information only/On or Off (user selectable): Step change, Phase change (user-selectable texts)
ALARMS OFF:	Information only with audible reminder (user selectable)

Storage

Period:	Approximately up to 1200 days with redundant server
Continuous:	12-lead ECG at 500 Samples/s @ 2.5 μ V LSB (optional)
12 lead average waveform:	every 5 s: 500 Samples/s @ 2.5 μ V LSB (optional)
Trends:	Heart rate, Ventricular rate, R-on-T rate, Couplet rate, Pause rate, Pacemaker Non-capture and Output Failure rates, PR-interval, QRS duration, QT interval QTc interval (Bazett + Fridericia), SpO ₂ , ST
Alarms:	Physiological alarms, clinical alarms, protocol events, 12-lead ECG printout events
RR-intervals:	2 ms resolution

Configuration

Storage Configurations:	1) Storage on local workstation 2) Storage on redundant (RAID1+0) server
Component Configurations:	1) Receiving workstation with support for up to 16 channels 2) Control workstation with support for up to 48 channels 3) Control and receive on one workstation 4) Control, receive, and storage on one workstation 5) Storage on redundant (RAID1+0) network server
Maximum number of telemetry channels per system:	Up to 128 channels per Surveyor Central system (more than one Surveyor Central system is required above 64 patients),

NOTE: Surveyor Central components are designed to share an independent physical network. Connection to an external network is through an optional VPN security router.

Network

Digital local area network:	IEEE 802.3, 100 Base T
Network protocol:	IP
Data exchange protocol:	UDP and TCP
Distance Switch-station:	Max 100 m
Cable:	8 wire twisted pair Cat 5
Connectors:	RJ-45
Router Firewall support:	ICSA Firewall, ICSA VPN, EAL4, 240 Mb/s throughput
Router VPN support :	VPN server, 40 Mb/s throughput
Router ports:	4 RJ-45 internal, 100 Base-T 1 RJ-45 external, 100 Base-T
Router IP addressing:	Fixed or DHCP

Size

Central Workstation:	35,6 cm x 16,9 cm x 43,5 mm (14.0 x 6.7 x 17.1 in)
Redundant Network Server:	46 x 22 x 74 cm (18.2 x 8.6 x 29.2 inches)
Monitor:	56 x 28 x 38 to 49 cm (22 x 11 x 15 to 19 inches) unpacked with stand
Printer	40 x 45 x 42 cm (16 x 18 x 17 inches)
Keyboard:	46 x 4 x 17 cm (18 x 1.5 x 6.7 inches)
Mouse:	13 x 6.4 x 3.8 cm (5 x 2.5 x 1.5 inches)
External Speakers:	15.8 x 6.8 x 6.4 cm (6.22 x 2.68 x 2.52 inches)

Weight

Central Workstation:	8.2 Kg (18.03 lb)
Redundant Network Server:	52 Kg (115 lbs.) Maximum (Fully Loaded Configuration)
Monitor:	6.8 Kg (15lbs.)
Printer	23.6 Kg (52 lbs)
Keyboard:	1 Kg (2.2 lbs.)
Mouse:	128 grams (4.5 oz.)
External Speakers:	0.4 Kg (1.41 oz)

Screen

Resolution with possible and recommended maximum number of monitoring slots per display:	19 “ Single Display 1280×1024 dots: 16 slots possible/ 8 slots recommended 24 “ Single Display 1920×1200 dots: 24 slots possible/ 16 slots recommended 19” Dual Display 1280×1024 dots: 32 slots possible/ 16 slots recommended 24” Dual Display 1920×1200 dots: 48 slots possible/ 32 slots recommended
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Traces per Patient:	Up to 12 on single-patient window, up to 2 on multiple-patient window
Parameters per Patient:	Up to 20 (user selectable)
Sweep traces:	10 or 25 mm/sec
ECG sensitivity:	5, 10, 20 or 40 mm/mV
Size:	19” or 24” LCD in single or dual display modes

Printer

Technology:	Black and white laser jet, networked
Printout types:	Rhythm, 12-lead ECG, ST report, Trends, End-of-Shift Report
12-lead ECG formats:	6x2, 3×4+1, 3×4+1+P, 3×4+3 @ 25 or 50 mm/s
Rhythm speeds:	5, 10, 25, 50 mm/s
Paper types:	A4 and Letter
Resolution:	1200 × 1200 dpi
Print speed:	55 ppm max

Electrical characteristics

Uninterrupted Power Supply:	Recommended for each workstation and server location
Power Supply	HP Z240 Workstation: 280 W HP Z2 G4 Workstation: 500 W HPE ML350P Gen 9 Server: 500 W HPE 380 Gen 10 Server: 800 W (2) 24” LCD Displays: 44 W USB Watchdog: 10 W Router: 15 W
Workstation UPS:	Required UPS USB HID (Human Interface device) compliant. - Recommended specifications (HP Z2 G4 Workstation) UPS rated for 800 VA (or greater) and with a runtime of at least 10 minutes at a 700 W or 760 VA load. - Recommended specifications (HP Z240 Workstation): UPS rated for 500 VA (or greater) and with a runtime of at least 10 minutes at a 420 W or 465 VA load.
Server UPS:	Required UPS USB HID (Human Interface device) compliant. Recommended specifications: UPS rated for 800 VA (or greater) and with a runtime of at least 10 minutes at a 700 W or 760 VA load.
Number of outlets needed:	2 or 3, per workstation, depending on system configuration

Voltage:	100-240 V
Rated Input Current	Redundant (RAID1+0) 7.1 Amps (at 120 VAC) to 3.5 Amps (at 240 VAC) per Power Supply

Redundant (RAID) Server Environmental Conditions

BTU Rating:	1773 BTU/hr (at 120 VAC), 1715 (at 240 VAC) w/ 460 W power supply
Transporting:	-30° to +60°C 10% to 90% humidity w/o condensation Maximum altitude of 9144 m (30,000 ft). Maximum allowable altitude change rate is 457 m/min (1500 ft/min)
Operating:	+10° to +35°C 10% to 90% humidity w/o condensation Maximum altitude of 3048 m (10,000 ft). This value may be limited by the type and number of options installed. Maximum allowable altitude change rate is 457 m/min (1500 ft/min).

Workstation Computer Environmental Conditions

BTU Rating:	Typical: 444 btu/hr (112 kcal/hr) Maximum: 1484 btu/hr (374 kcal/hr)
Transporting:	-30° to +60°C 10% to 90% humidity w/o condensation Maximum altitude 9,144 m (30,000 feet)
Operating:	+5° to +35°C 8% to 85% humidity w/o condensation Maximum altitude 3,000 m (10,000 feet)

SYSTEM RESTORATION

Disaster Recovery Procedure

System Node (non-server):

If a system node fails and the node must be rebuilt to restore system operation, the following steps should be followed.

1. Repair or replace the PC with materials defined in section 2 (System Overview) of this service manual.
2. Once the PC is operational, refer to document DIR-200150074 (SC PC Imaging, Application Loading, and Configuration) to re-image the PC to the factory configuration.
3. Add any site-specific configuration settings needed based on customer preferences and local IT information.
4. Perform system level conformance testing, per section 4 of this service manual to ensure the node restoration process has been completed successfully.

Redundant Storage Server:

If a redundant storage server fails and it must be rebuilt to restore system operation, the following steps should be followed.

1. Repair or replace the server with materials defined in section 2 (System Overview) of this service manual.

The redundant storage server is equipped with a Dynamic Smart RAID array of hard drives, which can be changed out with the system powered up, to automatically restore a defective drive in the array. If the failure is related to other hardware, the system should be powered down to repair a defective component.
2. If the server was repaired, no additional configuration work should be required, proceed to step 5.
3. If the server must be replaced, the new server will need to be set up and configured per MIS-12-169-00 section 8.
4. Add any site-specific configuration settings needed based on customer preferences and local IT information.
5. Perform system level conformance testing, per section 4 of this service manual to ensure the node restoration process has been completed successfully.

Database Backup:

To back up the DB perform the following:

1. Stop the SurveyorNetDBMS and Survsyslog services.
2. Backup folder C:\CENTRAL30DB to an external backup device.

Note: Since C:\CENTRAL30DB\Data is a mount point to the storage volume, the data content at C:\CENTRAL30DB\Data will need to be copied separately from the other C:\CENTRAL30DB files and folders.

Database restore:

Paste the C:\Central30DB\Data content into the new C:\Central30DB\Data folder.