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Application Note:

Electronic Health Record—Time Synchronization's Role in Regulatory Compliance

An Electronic Health Record (EHR) is a record containing confidential patient information in a paperless format. The record contains relevant patient information required by healthcare professionals. EHRs can be exchanged among offices and providers in a matter of seconds. Such records improve office workflow efficiencies, helping providers increase the quality of care given to patients.

Ease of accessibility and transfer increases the risks that electronic records may be compromised—both internally and by hackers from outside the network. This increases the need for network security and authentication. Whenever a patient's record is created or altered, there must be accountability. The healthcare provider must be able to track who created or edited the record, when these actions took place, and from where the information was accessed.

Policies and Regulations

Several policies and regulations are in place that affect the healthcare industry's handling of electronic records. These require providers to use computer-generated time stamps in support of audit trails. The time stamp proves when an action took place and can also authenticate digital signatures (which are considered legal forms of documentation).

Regulators such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) mandate that "every medical record must be dated, its author identified and, when necessary, authenticated."

The Health Level 7 (HL7) interoperability model is currently being revised to mandate time and date stamping for all EHRs. Part of the revision requires "traceability to, and time synchronization with, a master clock." This means providers must be able to prove that their time sources are accurate.

The Health Insurance Portability and Accountability Act (HIPAA) mandates authentication and security for EHRs. It defines access control, one of the parameters of which is time-of-day. The FDA (in 21 CFR Part 11, the federal regulation governing electronic records and electronic signatures) requires the use of such measures as "computer-generated, time-stamped audit trails."

Why Time Synchronization

How can a healthcare provider implement accurate timestamping for EHRs? The answer is time synchronization. When employing a time standard across the network and to all systems and devices in the facility, records and system operations are authenticated with Legally Traceable Time™. This standard must be accurate, reliable, and secure—both for facility-wide synchronization as well as to protect the confidentiality of patient records. If the time source is not accurate, it cannot be used to prove the exact time records were created, accessed, and revised. If the source is not reliable, there could be occasions in which the time stamp does not coincide with a database update, resulting in the potential loss of all new or existing information. If the source is not secure, hackers and other unauthorized personnel could gain access to the network and ultimately the records.

Why should a provider make this investment? With synchronized time, networks, systems, and operations run more efficiently. Log files are properly maintained and diagnostics improved with accurate time for sequence-of-events records. Personnel activities are better coordinated. Essential information (regarding treatments, procedures, cardiac trauma, births, and deaths) is safeguarded and its quality improved through accurate time keeping. Ultimately, time synchronization supports interoperability across the network and throughout the organization through cross-platform synergies.

NTP Time Servers

One method of time synchronization is to use public domain time servers over the Internet. This can result in a host of potential problems, however. No site is mandated for continuous 24/7/365 availability. Acquiring time in this way requires the continual opening of port 123 at the network boundary—disabling critical firewall protection through what is a well-known entry point in the hacker community. Public time servers are under constant hacker attack, even the Federal Government's NIST site (www.bldrdoc.gov/timefreq/time/authentication.htm). The site states quite plainly that "recent attacks against several Internet sites engaged in electronic commerce have raised concerns about the security of the NIST time servers and the authenticity of the messages they transmit."

NIST recommends, in several of its guidelines, that system clocks should be synchronized using Network Time Protocol (NTP). NIST further recommends that, for ease of use, organizations synchronize their time with NTP time servers.

The accuracy of most Internet time server sites is also suspect, as studies have shown in many cases that these site's time references are derived from a server's clock-time, without any true standard in place.

The best solution for time synchronization is a dedicated network time server. Such a device provides a common time source used by all devices on a network. It is a dedicated piece of hardware, not an

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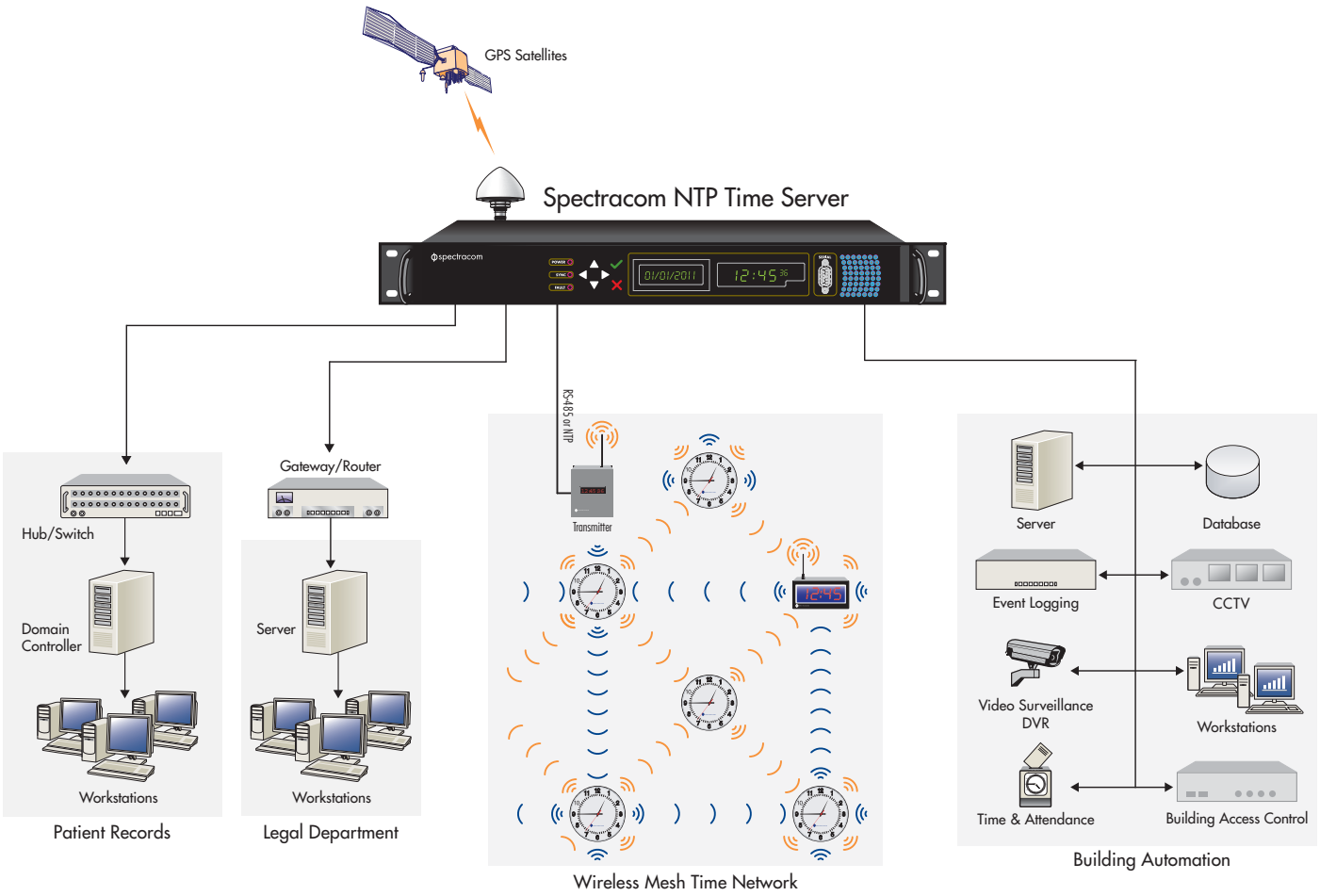
external source outside the control of the network owner. Installing a dedicated time server enables a healthcare provider to comply with healthcare regulations, policies, and mandates concerning time-stamping, audit trails, and authentication verification.

Spectracom offers its highly reliable, cost-effective time servers and master clocks to synchronize time across your network, receiving the official Coordinated Universal Time (UTC) through the Global Positioning System (GPS) signal. Spectracom operates behind the edge firewall, which means it requires no additional opened ports through which hackers could gain access to the system. NetClock uses industry standard Network Time Protocol (NTP) to distribute accurate, reliable, Legally Traceable Time™. A dedicated hardware time server from Spectracom supports the need for interoperability while synchronizing your critical operations.

Synchronized Healthcare Operations



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