IEC 60601-1
Network Isolators and Electrical Security in Hospital Networks
Safe and Secure Networks in Hospitals

Today’s medical facilities have highly diverse and complicated IT requirements. Systems used on a daily basis include picture archiving and communication systems (PACS), Hospital and Radiology Information Systems (HIS and RIS), Patient Data Management Systems (PDMS), Communication Server, alarm calls, digital signage and positioning, entertainment systems, IPTV, Wireless AP, mobile Visits, telemedicine and VPN. If we add IP based building automation and security management systems to the list, it will come as no surprise that more and more medical devices are being equipped with network interface cards. Vital sign monitors, ECG, glucometers, infusion pumps and central monitoring stations are just a few examples of medical networks merging with IT.

Figure 1. Intelligent managed LAN in Hospitals – Opportunities and Risks

These mixed medical/IT networks may introduce new risks that impact well-established processes in the hospital as well as patients’ health. Standards such as IEC 80001 and IEC 60601-1 require professional risk management in the hospital with a special focus on implementation and management of IT-Networks with integrated medical devices and systems.

This Technical Paper examines the use of intelligent managed switches with integrated galvanic isolators in medical environments based on TCP/IP. This type of medical switches guarantees maximum security and safety to both patients and equipment, whilst staying within tight budgets for procurement, management, service and maintenance.
Legal requirements regarding medical devices and systems

The hospital, as an operator of medical and data-processing infrastructure, is responsible for the electrical safety of equipment used. The hospital should conduct extensive risk assessment of all operated medical devices with a network interface card before they are introduced into the hospital network. It must be done to ensure whether they can operate in conjunction with non-medical devices (such as PCs, printers, monitoring cameras, etc.) on the same network.

This is where the globally recognized standard IEC 60601-1 applies. This standard defines general requirements for the safety and security of medical electrical equipment and systems in the hospital network which the manufacturer has specified for diagnosis, treatment or patient monitoring.

**IEC 60601-1 ‘Medical Electrical Equipment’ (excerpt):**

A medical electrical equipment (ME) is a device intended for diagnosing, treating, providing care to or monitoring patients and which is or can come into the direct contact with the patient.

A medical electrical (ME) system is a combination of several electrical devices, at least one of which is a medical electrical device.

The IEC 60601-1 standard classifies the network connection between a medical device and the Ethernet network as a potential source of danger. A leakage current can occur as a result of voltage differences between the grounding potentials of connected network components. This may have fatal consequences for the patient’s health.

Such voltage differences can be the result of faulty installation (for example through a contact between metal in data wires and conductive parts), misinterpretation of installation guidelines, aging, or moisture in copper-based networks.

**The use of unshielded cables is not a secure solution!** Such cables fail to provide galvanic isolation for data connections in accordance with hospital standards. Furthermore, they have a very bad EMC performance, which is inadmissible in medical applications.

In environments where these devices are operating in the direct vicinity of patients¹, safety requirements and regulations regarding the installation and operation of electrical equipment and systems are extremely stringent.

¹ Particularly where touchable conductive parts of the housing can come in contact, directly or indirectly, with the patient
a. Direct patient environment according to IEC 60601-1

The IEC 60601-1 standard includes the following definitions:

‘Patient environment ... is any area in which intentionally or unintentionally, an electrically conductive connection can occur, between the patient and parts of the ME device or ME system or between a patient and other persons touching parts of the ME device or the ME system... the patient is a living being (human or animal), which is subjected to a medical, surgical, or dental procedures’.

The IEC 60601-1 standard applies only to devices and systems which are in direct physical electrical contact with the patient (‘in the direct patient environment’).

![Diagram of patient environment]

Figure 2. Patient Environment: a radius of 1.5 m around the patient

In accordance with IEC 60601-1 network isolators must be used to separate all electrically conductive components between connected network devices and medical devices in Ethernet-based networks. The medical switch’s galvanic isolators separate the medical network from the data network and offer reliable protection against DC and AC voltages of up to 4 kV.

b. Network Isolators

Network isolators prevent the transmission of unwanted voltages and currents between parts of a medical electrical system. They are connected directly to the network interface, where power sources and dangerous leakage currents may occur.

Only network isolators provide sufficient protection against voltage differences and leakage currents\(^2\). IEC 60601-1 envisages that medical equipment which may come into direct contact with patients should be equipped with two independent safety protection measures. This ensures electrical safety, even in the event of failure of one of them.

---

\(^2\) If the manufacturer failed to provide any information regarding galvanic separation in the product documentation, it might be no galvanic isolation at all! In this case, you will need to procure a separate network isolator for each affected network interface and firmly fix it to the affected network device. The network isolator should be positioned as closely as possible to the device. The pull out risk should be excluded.
Furthermore, IEC 60601-1 defines different classes of insulation and creepage, leakage current and grounding depending on the desired MOOP- or MOPP Level.

\[ \text{MOOP} = \text{Means of Operator Protection} \]
\[ \text{MOPP} = \text{Means of Patient Protection} \]

<table>
<thead>
<tr>
<th>Classification</th>
<th>Withstand Voltage</th>
<th>Creepage</th>
<th>Insulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 MOOP</td>
<td>1500 VAC</td>
<td>2.5 mm</td>
<td>Basic</td>
</tr>
<tr>
<td>2 MOOP</td>
<td>3000 VAC</td>
<td>5 mm</td>
<td>Double</td>
</tr>
<tr>
<td>1 MOPP</td>
<td>1500 VAC</td>
<td>4 mm</td>
<td>Basic</td>
</tr>
<tr>
<td>2 MOPP</td>
<td>4000 VAC</td>
<td>8 mm</td>
<td>Double</td>
</tr>
</tbody>
</table>

According to legal regulations, it is vital to ensure the Ethernet connection between the network switch and the medical device is electrically isolated by a network isolator in accordance with IEC 60601-1. Network isolators can be divided into 4 classes, depending on the Level of Means of Protection, where 2 MOPP and withstand voltage of 4 kV currently stand for maximum protection.

Leakages flowing from the housing or component parts in an undesirable manner through the patient in the direction of Ground should not exceed the value of 0.5 mA according to IEC 60601-1.\(^4\)

The table below (from IEC 60601-1-1 for medical electrical equipment) describes various installation scenarios of medical and non-medical electrical equipment and their technical realization in the hospital network.

---

3 Due to increased risks for patients in contact with electrical or electronic equipment, safety requirements are higher for MOPP (means of patient protection) than for MOOP (means of operator protection).

4 Larger currents may have serious effects on the health of patients who are weakened, unconscious or anesthetized.
Table 1. ME-Devices and non-ME-Devices in various installation scenarios.  
Excerpt from IEC 60601-1

<table>
<thead>
<tr>
<th>Installation Scenario</th>
<th>Medical Room</th>
<th>Non-medical Room</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>In the patient environment</td>
<td>Outside of patient environment</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a. Devices A and B in the Patient Environment</td>
<td>![Diagram 1a]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1b. Devices A and B in the Patient Environment</td>
<td>![Diagram 1b]</td>
<td>For B: Additional protective ground or Isolator</td>
<td></td>
</tr>
<tr>
<td>1c. Device A, with power supplies from device B, in the patient environment</td>
<td>![Diagram 1c]</td>
<td>For B: Additional protective ground or Isolator</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2a. Device A in the Patient Environment and Device B in the medical room</td>
<td>![Diagram 2a]</td>
<td></td>
<td>For B: Clause 19.201</td>
</tr>
<tr>
<td>2b. Device A in the patient environment and Device B in the medical room</td>
<td>![Diagram 2b]</td>
<td></td>
<td>For B: Clause 19.201</td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3a. Device A in the Patient Environment and Device B in the non-medical Room</td>
<td>![Diagram 3a]</td>
<td>For B: Clause 19.201</td>
<td></td>
</tr>
<tr>
<td>3b. Device A in the Patient Environment and Device B in the non-medical room</td>
<td>![Diagram 3b]</td>
<td>For B: Additional protective ground or Isolator</td>
<td></td>
</tr>
</tbody>
</table>

Please Note:

- The blue fields represent medical electrical equipment, such as dental cameras, ultrasound equipment, special medical PCs and so on. These devices are compliant with IEC 60601-1.
- The red fields refer to general information technology equipment such as PCs, servers, printers, IP phones, etc. These are not IEC 60601-1 compliant. This is where a network isolator must be connected.
- The red and blue fields indicate that both versions (red or blue) are possible.

The optimal solution would be to exclusively use medical devices in hospital environments,
such as medical PCs, medical servers, medical laptops, and so on. Such devices are equipped with integrated isolators in accordance with IEC 60601-1 and do not require additional protection measures. This would lead to higher costs.

An alternative solution would be to provide each user port with a separate, standalone network isolator.

However, a more cost-effective, smarter solution is to use so-called Medical switches with integrated galvanic isolators. These not only ensure effective galvanic separation of grounding potentials, but also make the entire network easier to manage and maintain.

**First Gigabit Switch for Maximum Patient Safety & Security in Critical Infrastructures**

Switches are the cornerstone of a modern Ethernet network. They enable port duplication and efficient management of the network. Intelligent switches ‘know’ which devices and systems are connected to certain ports, and therefore send data packets to the ‘desired’ ports in a targeted manner. A modern switch has very low power consumption (less than 4 W) whilst still ensuring high data throughput (1 Gigabit per user port per second).

To meet the requirements of hospitals and medical facilities, in terms of powerful and secure IT infrastructures, the first ever ‘Medical’ switch was developed (under the name ‘LANactive Medical Switch’) with integrated built-in isolators according to IEC 60601-1.

**Technical Specification:**

- 4 integrated passive isolators for the user ports
- Patient protection of 2 MOPP with overvoltage protection of up to 4 kV
- Excellent electromagnetic compatibility (for use in laboratories, X-ray stations, in operating theatres)
• High power performance: guaranteed 1 Gigabit per second per user port
• Advanced IT security features (SNMPv3, IEEE 802.1x, RADIUS, SSH, HTTPS, etc.) and AES encryption (128 bit)
• MTBF over 400 years

In hospital networks, redundancy is of the utmost importance. Downtime or impairment of hospital IT services can have dramatic consequences for the health and wellbeing of patients. Therefore, hospitals have a special mission to ensure uninterrupted availability of their services and processes.

The LANactive Medical GigaSwitch enables enhanced redundancy and reliability concepts and is compatible with devices and systems from leading manufacturers in the field of medical and network technology.

Product Features:

• 4 integrated passive isolators for the user ports
• Enables advanced security concepts, including high availability and reliability
• Absolute redundancy
• Proven interoperability with the systems of leading medical hardware manufacturers and manufacturers of network components
• Noiseless
• Quality ‘Made in Germany’

Application: operating rooms and intensive care units, cardiology, surgery, radiation oncology, dentistry, etc. – wherever and whenever medical devices are connected to data networks and large data volumes need to be processed in a reliable, safe manner (particularly, DICOM, RIS).

Installation Scenarios: in cable ducts, communications columns, floor boxes and wall-mounting. The switch can be elegantly integrated into the existing environment. It is easy to clean and to disinfect.
Benefits:

- Meet all the latest technical requirements for IT network communications and security
- Reduced risk management
- Switches are inseparable part of the existing network infrastructure
- Intelligent and manageable
- Enhanced redundancy concepts enabled
- Optional antibacterial coating
- Compatible with systems from leading medical equipment manufacturers
- Best Anti-Hacker Protection: secure network, secure data

A comparison between standalone network isolators and the switch with integrated insulators can be found in the appendix at the end of this document.

Conclusion:

- The switch relieves hospital staff from the task of ensuring galvanic isolation of network interfaces and carrying out risk assessments every time a new device is connected to the network.
- Particularly in large medical institutions, the Switch will help reduce the administrative burden. It is, therefore, a cost-effective solution which saves time, money and manpower.

Please Note: No power supply is required; the switch is connected directly to 230 VAC.

Examples of Usage

The LANactive Medical GigaSwitch is an Access Level Switch. This is an application device for port multiplication and network extension. LANactive Medical GigaSwitches can be used in traditional Twisted Pair copper networks, but also in fibre-optic cabling technologies such as Fibre To The Office (FTTO).

![Figure 3. Some installation scenarios](image-url)
### When should the ‘Medical’ Switch be used?

| 1b. Devices A and B in the Patient Environment | A | B | Multiple devices, both medical and non-medical, in the direct vicinity of the patient, in the same medical room. |
| 2b. and 3b. Device A in the Patient Environment and Device B in the medical or non-medical room | A | B | A medical device is in the patient direct environment and a non-medical device (e.g. PC, printer or fax machine) outside of the patient environment, but in the same medical or non-medical room. |

An example of a LANactive Medical GigaSwitch in an FTTO\(^5\) network can be found below:

![LANactive Medical GigaSwitch in an FTTO Network](image)

*Figure 4. LANactive Medical GigaSwitch in an FTTO Network*

---

\(^5\) Fibre To The Office, learn more at [www.nexans.co.uk/lansystems](http://www.nexans.co.uk/lansystems)
Closing Remarks

Nexans LANactive Medical GigaSwitch meets and exceeds the requirements of the IEC 60601-1 standard.

The switch has four built-in passive isolators for electrical separation of medical and technical data networks. It provides a standard-compliant surge protection of up to 4 kV, is noiseless and enables smooth Ethernet communication without packet loss and jitter in a highly sensitive environment.

The switch ensures a safe and cost-effective connection of the digital medical equipment (such as ECG, patient monitoring systems, infusion pumps, blood glucose meters, vital data monitors and other vital electronic devices) to the hospital’s data network.

The Switch can be installed in the direct patient environment (within 1.5 m of the patient).
Appendix

A. Is the use of a switch more useful or sensible than the use of a standalone network isolator?

The table summarizes the advantages and disadvantages of each option.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standalone Network Isolator</th>
<th>Switch with Integrated Isolators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Channel Length</td>
<td>Limited, typ. 60-80 m</td>
<td>Full 100 m guaranteed for TP Ports</td>
</tr>
<tr>
<td>Communication</td>
<td>Lossy communication, Return Loss and attenuation of several dB</td>
<td>No signal loss</td>
</tr>
<tr>
<td>IEC 11801 Channel Model</td>
<td>Network isolators are not envisaged in a cabling channel. No quality assessment is possible.</td>
<td>Full conformity</td>
</tr>
<tr>
<td>Infrastructure</td>
<td>Easy to remove, risk of loss or damage</td>
<td>Integral part of the infrastructure</td>
</tr>
<tr>
<td>Risk Management</td>
<td>Increased risk: for example, the risk of touching incoming, unprotected wires in the direct environment by the patient, by the doctor or by the nursing staff. Additional protection and shielding are necessary.</td>
<td>• Integrated insulation module -&gt; no risk of loss, extraction or short circuit&lt;br&gt; • Drastic reduction in cabling volume, more flexibility for the operation room&lt;br&gt; • Monitoring and Diagnostics Function of TP- und Optic fibre Links</td>
</tr>
<tr>
<td>Solution</td>
<td>• Risk Management&lt;br&gt; • A Network Isolator per network interface -&gt; the more interfaces and ports there are, the more isolators are required, and the higher are the costs</td>
<td>• Risk Management only for the Switch&lt;br&gt; • 4 integrated Isolators in the Switch -&gt; 4 galvanically separated devices</td>
</tr>
</tbody>
</table>

Procuring 4 standalone network isolators is considerably more costly than procuring a switch with four integrated isolators!

B. Conclusion of A

Switches with integrated passive isolators are a standard-compliant solution. A single switch backs up to four connected devices, possibly even all of the devices in the medical room. Therefore, non-medical equipment may be operated in a network together with medical equipment. ‘Default’ standard office computers, monitors and printers can be used instead of Medical PCs, Monitors, and printers. There is no need to carry out extensive risk assessment and there are no packet or signal losses. The hospital benefits from drastically reduced administrative costs and the high level of flexibility offered by the solution.
Comments
Comments