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Tata Elxsi's Solution Suite for Tackling the Challenges for Wireless Technology in Healthcare

A Tata Elxsi Perspective

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Abstract

In spite of the ubiquity of wireless technology in the medical device domain, the expertise and guidance in this field are still lagging. Tackling these challenges require focused effort from all the stakeholders, as it is important to ensure patient safety, follow the statutory and regulatory standards, ensure security and integrity of crucial medical data, availability and reliability of the wireless network. This paper attempts to analyze the risks, challenges and opportunities of wireless technology in healthcare and how Tata Elxsi's suite of solutions for medical device manufacturers.

Status Quo

The proliferation of wireless technology in healthcare provides endless possibilities to improve the quality of life, efficiency and continuity of care at reduced costs while extending access to health care outside the clinical setting. This enhanced clinical workflow is driving towards better preventive care. In addition to this "Bring Your Own Medical Device" (BYOD) is also a possibility which will be the outcome of the connected healthcare revolution. Tech savvy patients and physicians will bring in a wide range of wireless devices and applications which may cause serious problems with the wireless infrastructure if not managed well.

Data Points

- Forty-five percent of clinicians say they are using mobile technology to collect data at the patient bedside in 2012, up from 30 percent in 2011
- Half of clinicians say they will be using more mobile medical apps in the next year
- Three-quarters of organizations say they will be using more mobile devices, specially tablets, in the future
    - *2nd Annual HIMSS Mobile Technology Survey, 2012*
- Sixty-nice percent of the nurses interviewed say that nursing staff use their personal Smartphones on the job, particularly to fill "critical communication gaps: with hospital IT
- Twenty-five percent of nurses say that they are dissatisfied with the quality and reliability if the wireless network in their facilities
    - *Point of Care Computing for Nursing 2012, Spyglass Consulting Group*

Correct and timely transmission of medical data and information is essential for the safety and effectiveness of both wired and wireless medical devices and systems. As mentioned by Elliot Sloane, President of the Center for Healthcare Information Research and Policy, managing the wireless infrastructure is a challenge, given the wireless Tsunami ahead of us. The recently concluded AAMI session on wireless connectivity for medical applications, prioritized the challenges into five themes:

1. Clarify roles and responsibilities
2. Manage the wireless spectrum to improve safety and security
3. Ensure high reliability of the wireless infrastructure
4. Adapt and learn from other industries
5. Risk management and failure prevention and provide top priority to patient safety

Top Ten Common Mistakes in Implementing the Wireless Technology in Healthcare

AAMI identified the following as the top ten common mistakes in implementing the wireless technology in healthcare:

1. Underestimation of potential risk to patients
2. Lack of planning in the implementation of wireless technology
3. Decision making with false assumptions
4. Failure to consider the limitations of the current infrastructure
5. Failure to design with safety margin or not ensuring essential performance
6. Failure to manage changes (like firmware change may affect performance)
7. Failure to perform vendor site testing of the network
8. Failure to consider all intended use scenarios
9. Failure to perform routine maintenance
10. Failure to consider that construction projects or physical changes to a facility can change wireless performance

Wireless Standards - Overview

The current RF wireless technologies include:

- 47 CFR Part 15 (Federal Communications Commission (FCC Part 15) devices
- Wireless Medical Telemetry

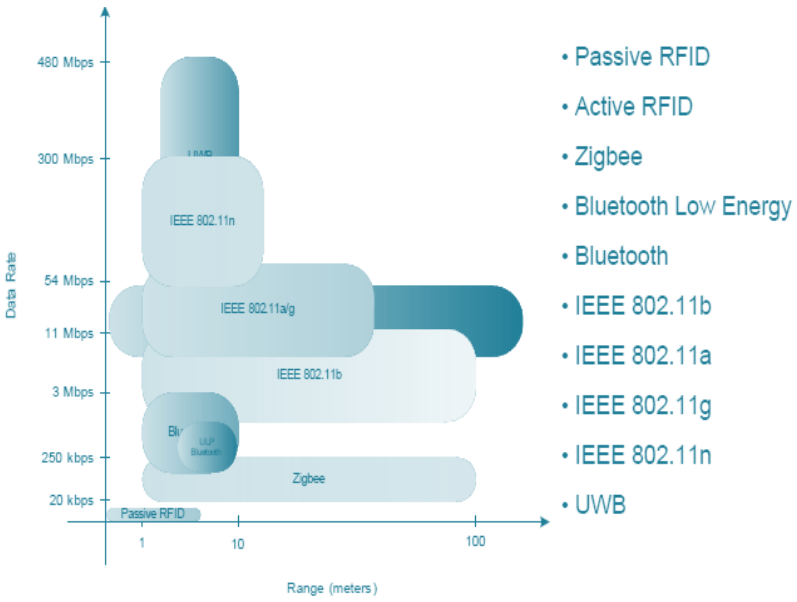


Figure 1. Potential wireless standards for medical applications source: Texas instruments

Service (WMTS)
- Cellular (mobile) telephones
- Wireless handheld computers and personal digital assistants (PDAs)
- Wireless local area networks (WLAN 802.11.a/b/g)
- Wireless modems for laptop computers
- Personal area networks, including 802.15.1 (Bluetooth), 802.153a (ultra wide band) (UWB), and 802.15.4 (ZigBee)
- RF identification (RFID)

Performance Parameters Related to Wireless Technologies

Quality of Service (QoS):

QoS refers to the capability of a network to provide better service to selected network traffic over various network technologies. QoS enables network resources to be shared more efficiently and expedites the handling of mission-critical applications. QoS manages time-sensitive multimedia and voice application traffic to ensure that this traffic receives higher priority, greater bandwidth, and less delay than best-effort data traffic. While the quality of service of cellular networks may be acceptable for voice communication, it may not be sufficient for medical functions. Connections lost without warning, failure to establish connections, or even slight degradation of service can have serious consequences.

Integrity of Data Transmitted Wirelessly

Many RF wireless devices use the industrial, scientific, and medical (ISM) frequency bands such as 2.4GHz, and these can incorporate technology to minimize interference and data errors or corruption (e.g., RF frequency hopping protocols). However, wireless coexistence and data latency remain causes of concern because the data transfer rate can slow slightly or even dramatically with an increase in the number of similar transmitters in a given location. In many cases it is essential that medical data, including real-time waveforms and critical control signals and alarms, be transmitted and received without error.

Security of Data Transmitted Wirelessly and Wireless Network Access

Security is a concern in the use of RF wireless technology because it can be easier for unauthorized eavesdropping on patient data or unauthorized access to hospital networks to occur.

EMC

FDA recommends Electromagnetic Compatibility (EMC) be an integral part of your design, testing, and

performance of the RF wireless medical devices. Voluntary consensus standards such as the IEC 60601-1-2:2001 "Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests" (IEC 60601-1-2:2001) provide electromagnetic emissions and immunity requirements for medical electrical equipment. However, as noted above, RF receivers are exempt in this standard from immunity provisions in their pass band.

Wireless Coexistence

Wireless coexistence can be defined as the ability of multiple heterogeneous wireless systems to share the same or adjacent frequency spectrum without undue interaction or interference affecting the performance and transmission or reception of signals and data. Coexistence is a growing concern in wireless communication standards. One of the first standards that dealt with coexistence was 802.16.2-2001, which recommended guidelines and deployment practices for minimizing interference between fixed broadband wireless access systems. It covered frequencies from 10-66 GHz and was superseded by IEEE 802.16.2-2004. The IEEE 802.15.2-2003 recommended practices for coexistence among personal area networks and other selected wireless devices operating in unlicensed frequency bands.

In the same year, IEEE 802.15.4-2003 recommended factors that should be taken into account to allow for coexistence. Annex E. IEEE 1900.2-2008 [7], recommends interference analysis criteria for measuring interference between wireless systems. It lists an exhaustive list of coexisting factors in the physical layer and medium access control layer that should be taken into account. The standard also suggests a structure for a coexistence report.

The IEEE 802.19 Wireless Coexistence Working Group is a technical advisory group that was created based on the success of 802.15.2, to act as a coexistence advisory committee, across all of IEEE 802. Its primary focus is IEEE 802 standards operating in the unlicensed bands. Currently, the 802.19 working group is developing a recommended practice for methods to assess the coexistence of wireless networks. Each of these standards [3-8] work analytically, laying out guidelines for determining coexistence; however, lack experimental coexistence setups to evaluate interference among the standards. To address the above concern, the American National Standards Institute (ANSI) C63, subcommittee 8 formed a working group to seek solutions, known as C63.27.

Since it is extremely important to ensure that medical data, including real-time waveforms, critical control signals and alarms, be transmitted and received without error, it is crucial to ensure that a medical wireless system performs its tasks without compromising on the quality of service in a shared wireless environment.

Coexistence Solution

A solution to the coexistence problem largely depends on the technology employed by the medical devices. Medical devices need to be tested for risks involved when exposed in a multiple RF signal environment.

To support the manufacturers' claim for safety, the FDA demands that manufacturers furnish details related to the capabilities of their devices to operate properly in an electromagnetic environment without interfering with other devices.

The wireless coexistence problem is growing, not just among medical devices, but also among various consumer electronic devices operated using various standards. Some standards have defined testing methods for testing co-existence. For example the co-existence of Bluetooth and WiFi, both operating in 2.4GHz band is a classic problem and has been addressed by various chip manufactures.

Various interference analyses have been carried out in an environment involving WiFi, ZigBee and Bluetooth. The outcome of these analyses has found that with devices operating at normal power, no significant loss of packets was observed, however with increased power levels, performance does suffer.

Medical devices have tried to employ various techniques like retransmission of packets, error correction techniques to overcome the problems caused due to interference.

Many standards have formed working groups to address the problem of interference involving their standard with others. The IEEE 802.19 [6] is the wireless coexistence Technical Advisory Group that addresses coexistence between wireless standards within IEEE 802 (WLAN, WPAN).

As there has been no standardization to address the risks associated with co-existent RF medical devices, different manufactures use different techniques to evaluate wireless co-existence.

Medical devices supporting the wireless technology need to be tested with standards like IEC 60601- 1-2 for EMC testing [3] which basically addresses the safety of medical devices which are non-im¬plantable. However the standard does not define requirements to fully address the risks involved as a result of wireless coexistence even if wireless transmission is the primary function of the device.

In spite of there being no standards available to solve the co-existence problems, device manufactures can follow few recommendations while designing and testing their devices. These include:

- Ensuring that medical devices (including cables, sensors, and electrical accessories) are not exposed to ambient RF fields that exceed RF immunity standards can help prevent EMI problems
- Proper floor planning for both new and existing facilities, and for units in which particularly sensitive devices are used such as fetal heart monitors, EEG, etc. These devices should not be located near areas where intense RF emissions can occur, including imaging systems, elevators, or electro-surgery suites.
- Ensure RF transmitters are used in properly shielded rooms that are lined with adequate RF absorbing material.
- Proper selection of wireless

standard that is the best fit for the intended use of the product5

FDA has recently released a draft guidance on using wireless technology in medical devices which emphasize on safe, effective, reliable and secure medical devices. A key factor contributing to a wireless medical device's safety and effectiveness is the limited amount of RF spectrum available and potential competition among wireless technologies for the same spectrum. This is managed in different ways for different RF wireless communication technologies that may be available for use in healthcare communication and health informatics exchange. FDA recommends addressing the selection of appropriate RF wireless communication technologies in the design and development process, including it as part of the risk management process.

Risk Management

IEC 80001 Application of Risk Management for IT-Networks Incorporating Medical Devices

The goal of IEC 80001 is to apply appropriate risk management consistent with ISO 14971 to address the key properties of safety, effectiveness, data and system security and interoperability. These properties are considered necessary to maintain the well-being of the patient. The standard recognizes that risk management must be applied throughout the life cycle of the network- that is, through all the changes that occur during the life of the network. The first draft of IEC 80001 included requirements for the roles, responsibilities, and life cycle risk management process needed to address the key properties for networks with medical devices Risk management

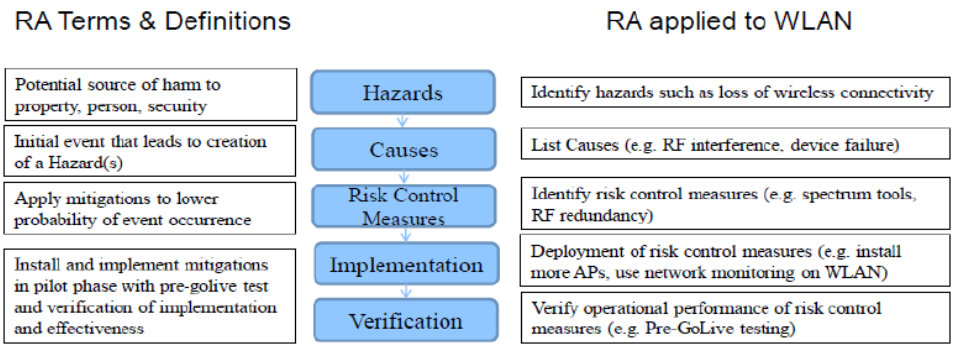
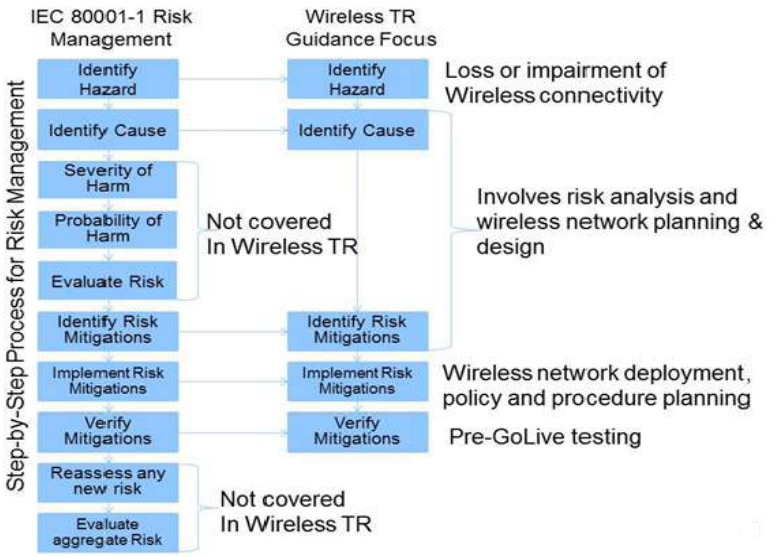
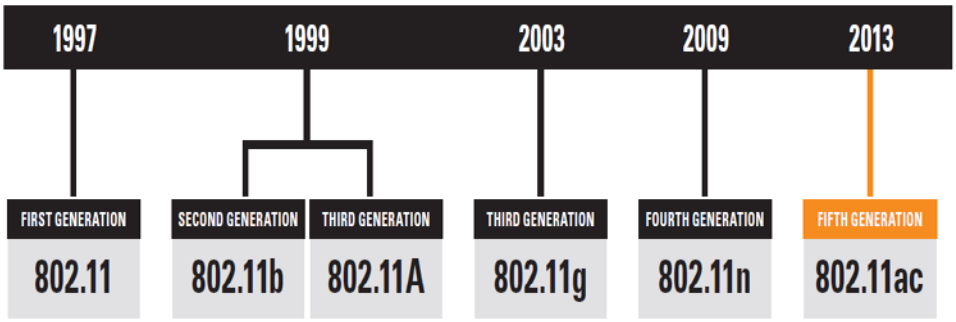


Figure 2. Step by step risk management process





is a valuable tool in identifying the networking requirements of your hospital and best practices and network management processes that are key in providing the medical IT network that meets these requirements.

Future of wireless in Healthcare

IEEE 802.11 AC

802.11ac, the emerging standard from the IEEE, is a faster and more scalable version of 802.11n. 802.11ac couples the freedom of wireless with the capabilities of Gigabit Ethernet. The main goal of the new 802.11ac is to significantly increase the throughput within the Basic Service Set (BSS).

The official target rates, as defined at the start of the project, are at a maximum Multi-Station (Multi-STA) throughput of at least 1 Gbps and a maximum single link throughput of at least 500 Mbps. These higher rates are motivated by the continuing trend to transition devices and applications from fixed links to wireless links and by the emergence of new applications with ever higher throughput requirements.

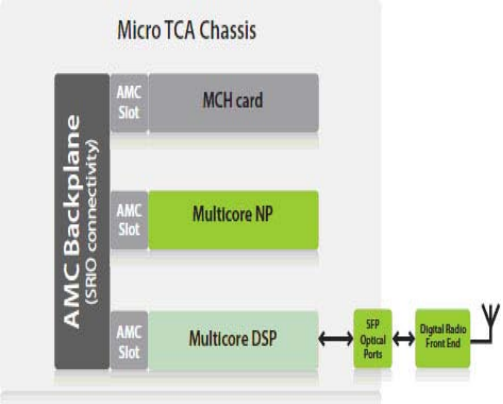
The existing 802.11 technologies operate in the 2.4 GHz band (802.11b, 802.11g), the 5 GHz band (802.11a), or both (802.11n). 802.11ac operates strictly in the 5GHz band, but supports backwards compatibility with other 802.11 technologies operating in the same band (most notably 802.11n).

New products based on the next-generation 802.11ac wireless networking standard, that offer data transfer speeds of up to one gigabit per second are already being adopted around the world by hospitals, will enable them to support the growing number of devices connected to their wireless networks and the high performance of high-bandwidth applications, such as HD streaming video, web conferencing, and data backup and transfers. Operating in the 5GHz range, 802.11ac allows customers to provide end users with greater speeds and access to more bandwidth-intensive applications.

Tata Elxsi's Wireless Capabilities

Tata Elxsi offers fully integrated LTE reference designs and services based on the leading hardware platforms. Our solutions are scalable to address

various product requirements, ranging from Femto to Macro eNodeB. Our



Small Cell solutions deliver platform optimized L1 and L2 /L3 software protocol stacks with industry leading performance, providing time-to-market advantage to network equipment manufacturers. These have been implemented on the latest semiconductor platforms from Texas Instruments, Freescale semiconductor, Cavium Networks, Xilinx, etc. are and licensed to OEMs globally and integrated with various Radios from different manufacturers.

Our LTE eNodeB solution is fully compliant to the 3GPP specifications and is tested for interoperability with the leading test and measurement products and third party UE devices.

Our vast experience and proven expertise in small cell technology development makes us a partner of choice to provide next-generation customizable solutions. We are working with leading OEMs worldwide with committed roadmap to support 3GPP Release 9 and Release 10 specifications.

Tata Elxsi's Reference design

Tata Elxsi's LTE system software, comprising the PHY, MAC, RLC, PDCP, Scheduler, RRC, S1AP, X2AP, GTPu and SCTP, is a key component for building LTE Femto, Pico and Macro eNodeB.

Our software is integrated, optimized and benchmarked for performance on leading multi-core DSPs and processors. This is integrated with radio and is available on Commercial Off The Shelf (COTS) platform based on the chipsets.

Key Features:

- Integrated solution on COTS hardware
  - L2/L3 IPR
  - L1 on Freescale/TI platform
- Supports FDD & TDD
- Release 9 compliant - SON framework, O&M based on TS32.592/3 and Small cell Forum compliant L1-L2 interface
- Interoperability with Signalion / Qualcomm UE, Polaris Networks/ Hitachi EPC
- Service Access Point (SAP) based implementation
- Full featured scheduler implementation – Latency priority, proportionate Fairness
- Solution integrated with various partner radios
- Flexible/customizable deployment options for L2/L3 IPR
- DL MIMO 2X2

Tata Elxsi also provides custom product engineering services including hardware design and full product development and maintenance.

LTE User Equipment Solution

Tata Elxsi provides a complete LTE solution with UE PHY and L2/L3 protocol stack integrated various Radios from different manufacturers. Our solution complies fully with 3GPP Release 8. Our LTE protocol stack has completely optimized Layer 2, Layer 3 with the best of the industry uplink and downlink data rates.

Key Features:

- Integrated Solution on COTS hardware
  - L2/L3 IPR
  - L1 on TI platform
- Supports FDD & TDD
- Release 8 compliant
- IOT with third party EPC, Tata Elxsi eNB
- TDD & FDD support
- Solution integrated with partner radios
- Supports category 3

Service Access Point:

MCAL - Multi Core Abstraction Layer

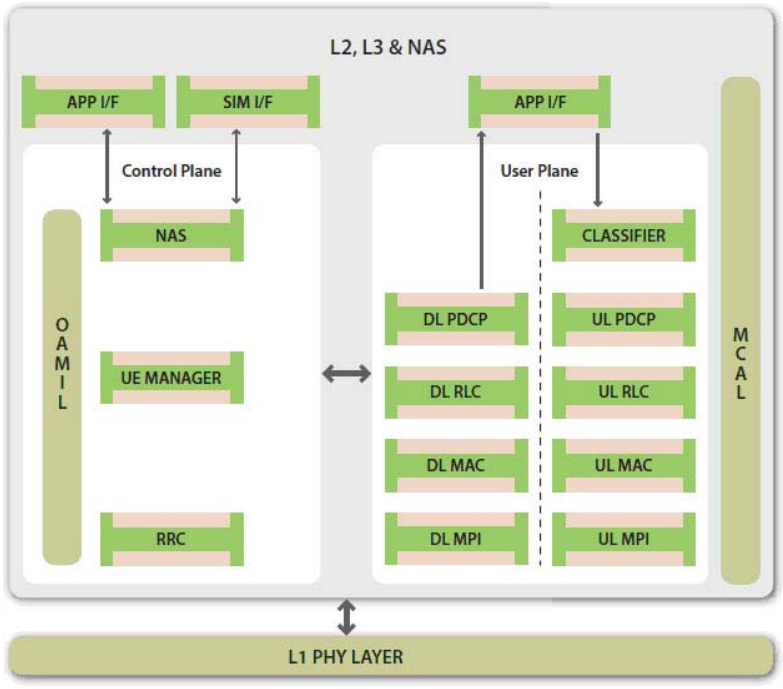
OAMIL - Operation & Maintenance Interface

Layer:

APP I/F - Application Interface

SIM I/F - Subscriber Identity Module Interface

Tata Elxsi provides professional services for development and customization, porting, integration and complete independent test validation from lab tests to field trials.



Conclusion

Addressing the wireless implementation challenges requires a concerted effort of many stakeholders. Interference between wireless electronic devices and medical equipment is a growing problem in the healthcare which should not be ignored by healthcare organizations. Current methods supported by manufacturers for testing coexistence are based on ad-hoc tests, and no uniform standard or consensus has been adopted by manufacturers to address the risks associated with medical devices. However, healthcare organizations can successfully manage and mitigate wireless interference at appropriate levels by following the best industry practices and adopting policy guidelines recommended by the government, relevant associations and institutions. New wireless standards and technological innovations will catapult wireless capabilities to a newer height and its impact on medical technology will change the face of modern healthcare.

About the Author

Vimal Kumar has 23 years of experience in Biomedical design, automated functional testing of Aircraft engines and turbines and also techno commercial business development. He holds an Indian Patent (No: 3035/CHE/2010) for the smallest 3 lead ECG machine. He leads TATA ELXSI's medical electronics Solution team which plays a pivotal role in conceptualizing and developing service offerings for the medical device domain.

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Contact us

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About Tata Elxsi's medical devices engineering services offerings

Tata Elxsi provides design and engineering services to the medical device industry. We understand the changing trends in this industry and offer services such as concept generation & validation, product development, verification & validation, and sustenance engineering.

With a unique focus on product design and engineering services, we provide services across the product development lifecycle. We have leveraged our cross functional domain expertise in the areas of connectivity technologies (Bluetooth, Wi-Fi, wireless), mobility solutions, and industrial design to provide cutting edge solutions to our clients spanning Diagnostic & imaging, ventilator, infusion pump, therapeutic, surgical equipments, point of care, endoscopy, diabetes devices and tele-health solutions.

About Tata Elxsi

Tata Elxsi is a design company that blends technology, creativity and engineering to help customers transform ideas into world-class products and solutions.

A part of the $100 billion Tata group, Tata Elxsi addresses the communications, consumer products, defence, health care, media & entertainment, semiconductor and transportation sectors. This is supported by a network of design studios, development centers and offices worldwide. Key services include embedded product design, industrial design, animation & visual effects and systems integration. Tata Elxsi is a listed company and headquartered in Bangalore, India.

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