



Industry Solution
Medical

ENSURE SAFE MEDICAL DEVICES AND SECURE PATIENT DATA - Software-based medical devices increase efficiency in health care. Non-critical treatments can be done by Linux-based systems whereas critical treatments with highly effective drugs, diagnostic imaging procedures or minimally invasive surgeries have to meet strictest Safety and Security regulations.

PIKEOS HYPERVISOR FOR MEDICAL DEVICES

The PikeOS Hypervisor provides a modular system architecture that integrates multiple applications on a single hardware. PikeOS is a full RTOS, virtualization and partitioning system designed to support highest requirements of medical devices and applications. It consists of a small, certifiable microkernel, upon which the hypervisor provides separated partitions for broad resource and function needs in safe individual partitions.

A virtualization infrastructure provides GuestOSs ranging from Native PikeOS to POSIX and Linux. Diverse applications can be hosted in separate partitions to allow concurrent operation of applications with different Security levels, Safety classes, and real-time operations on a single standard hardware. This addresses the segregation approach, which is defined in the IEC 62304 in order to achieve risk control.

CERTIFICATION SUCCESS INCLUDED

When critical Medical applications have to be compliant to Safety standards such as IEC 62304 and/or follow FDA Medical device regulations, PikeOS is the best choice for three reasons: Small size, criticality partitioning, and unparalleled company support for the certification process.

Purpose-built to meet highest certification requirements, PikeOS is implemented with a partitioning concept which enables the certification of applications of various levels of criticality to their individual Safety levels while running securely separated on one hardware platform.

Equally important for certification is a competent and reliable partner when it comes to planning, documentation, verification, validation and quality assurance processes. For over 25 years, SYSGO supports its customers with certification expertise, training workshops as well as full process artifacts and source code kits for system certification activities.

"We pay a lot of attention to the different hardware and software components used in our products. We are convinced that SYSGO offers not only the right technology but also the right team to support our business model."

Dr. Clara Cavalier,
Senior Product Manager Cell Biology at Hamiltonas

WHY PIKEOS FOR MEDICAL DEVICES

Medical devices for critical treatments must comply with highest Safety as well as Security regulations. Of prime importance, the life and health of patients may not be endangered. Furthermore, their personal data must be protected against unauthorized access. Its unique properties make PikeOS a reliable and efficient foundation for critical Medical applications:

1. Reduced complexity saves weight, space and cabling: PikeOS enables integration of a large number of electronic devices onto a single hardware platform.
2. Secure communication protects subsystems: Strict separation of applications into secure partitions allows authorized access only and avoids mutual interference.
3. Integrated Safety reduces certification costs: Applications of various levels of criticality and Security are safely separated from each other in distinct partitions and certified separately.
4. Extreme flexibility provides independence from suppliers in the choice of hardware and software: PikeOS supports a broad range of hardware architectures and provides interfaces for a wide array of GuestOSs. Adding other architectures and interfaces (incl. legacy code) is easy.
4. Multiple Independent Levels of Security (MILS) architecture: The PikeOS separation kernel controls communications and provides protection against malicious attacks. The PikeOS hypervisor is certified according to Common Criteria EAL3+. Read more → www.sysgo.com/common-criteria
5. Expandability saves costs in downstream incremental development: Partitions are simple to configure in the development phase and can even be supplemented and expanded with new applications after entry into service.

INDUSTRY ECOSYSTEM AND COLLABORATIONS

Medical device projects use a wide range of software and hardware products. Flawless interaction between the components used is vital to the success of complex projects. For this reason, we have been working in close collaboration

PIKEOS GUEST OS

Partitions can host different GuestOSs, run-time environments (RTE) and APIs, which run in non-privileged mode, on top of the PikeOS Hypervisor.

Medical GuestOSs include:

- Linux · PikeOS Native
- POSIX

MEDICAL ARCHITECTURES (SINGLE & MULTI-CORE)

- ARM · SPARC V8 · MIPS
- PowerPC · x86

THE ECOSYSTEM

- aicas · ARM · Atego
- Esterel · Freescale
- Infineon · Intel · Kontron
- Lauterbach · MEN · MIPS
- Rapita · Renesas · Vector Software · Xilinx

MORE CUSTOMERS AND PARTNERS

- B. Braun · Eckert & Ziegler · Fresenius
- Hamilton · Roche

with the leading global Medical technology suppliers for many years now. We support a wide selection of hardware platforms with our software products and have developed interfaces for code generators and analysis tools which are constantly being expanded.

PIKEOS IN ACTION: B. BRAUN'S INFUSION SYSTEM

The B. Braun Space infusion system represents the latest technology available to manage complex infusion therapies with up to 24 pumps integrated into the space station and linked to the space server or to the clinical information system. Linux-based interfaces include Ethernet, RS232, USB master/slave, Wi-Fi, and bar code scanner to be used with any standard internet browser. The innovative design has resulted in a single pump platform that covers the entire spectrum of infusion therapy types (e.g. general infusions, PCA, TCI, etc.).

Read more → www.sysgo.com/braun_infusion

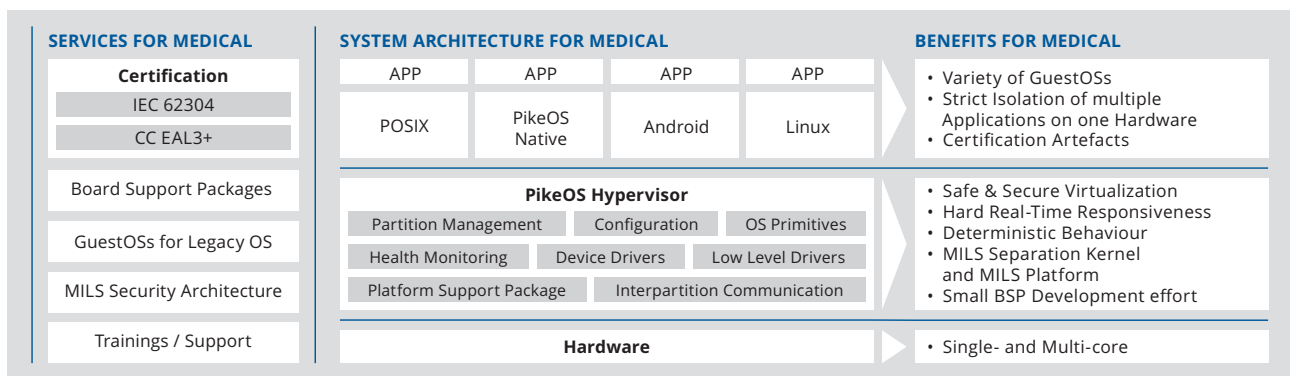


Figure 1: Scheme of a Medical System with PikeOS Architecture

Founded in 1991, SYSGO became a trusted advisor for Embedded Operating Systems and is the European leader in hypervisor-based OS technology offering worldwide product life cycle support. We are well positioned to meet customer needs in all industries and offer tailor-made solutions with highest expectations in Safety & Security. More information at www.sysgo.com/medical