


 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. Critical treatments with highly effective drugs, diagnostic imaging procedures or minimally invasive surgeries must meet safety and security regulations.

PIKEOS HYPERVISOR FOR MEDICAL DEVICES

PikeOS is a software platform that supports critical requirements of medical devices, such as real-time responsiveness, determinism, safety, security and diverse hardware and software support. Basis of PikeOS is a small, certifiable micro-kernel, upon which a virtualization infrastructure provides so-called personalities ranging from native to POSIX and Linux. Diverse applications can be hosted in separate partitions. Separation technology allows 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. The PikeOS separation technology has proven its maturity over several industries and is a perfect means to separate different safety classes and isolate software of unknown pedigree.

CERTIFICATION SUCCESS INCLUDED

Critical medical applications must be compliant to safety standards such as IEC 62304 and/or follow FDA medical device regulations. PikeOS is the best certification solution

for three reasons: small size, criticality partitioning, and unparalleled company support for the certification process. As PikeOS is purpose-built to meet these requirements, its main features are implemented in about 10,000 lines of code. Its partitioning concept enables the certification of applications to their individual required safety levels while running securely in parallel on the same hardware. Equally important for certification is a competent and reliable partner when it comes to documentation, requirements and tests. For over 15 years, SYSGO supports its customers with own resources, know-how, engineers, workshops and training, as well as with artifacts and provision of source code.

"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 Cavelier,
 Senior Product Manager Cell Biology,
 Hamilton

WHY PIKEOS FOR MEDICAL DEVICES

Medical devices for critical treatments must comply with 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. Support for a broad variety of personalities allows consolidation:** PikeOS can be used in complex mixed-critical applications where Linux based graphic or network functionalities run concurrently with POSIX based safety-critical and time-critical medication applications in separate partitions on a single processor.
- 2. Integrated safety and security reduces certification costs:** Applications of various levels of criticality and security are safely separated from one another in distinct partitions and certified separately.
- 3. Extreme flexibility provides independence from suppliers in the choice of hardware and software:** PikeOS supports a broad range of hardware and software. It is easy to add additional architectures and interfaces (including for legacy code).

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 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 PERSONALITIES

Partitions can host different personalities, i.e. guest operating systems, run-time environments (RTE) and APIs, on top of the hypervisor running in non-privileged mode. Medical technology personalities include:

- Certified POSIX · Native
- Linux · POSIX

THE ECOSYSTEM

· aicas · ARM · Atego

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

MEDICAL ARCHITECTURES (SINGLE & MULTI-CORE)

- ARM · SPARC V8 · MIPS
- x86 · PowerPC

MORE CUSTOMERS

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

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.).

