

# **Cybersecurity-by-Design Medical Care and Life Sciences**

- Protecting digital assets
- Safeguarding medical devices
- Monetizing e-Health



# **Foreword**



Medical technology, healthcare, or life sciences: At Wibu-Systems, we are proud that our technologies and innovations are favored by many leaders in the field. Here, our promise of reliable and trustworthy, protection, licensing, and security comes true in the best sense: Our CodeMeter technology helps protect not only the IP and commercial success of tech-forward enterprises, but the health and wellbeing of people everywhere.

Years of creativity and cutting-edge research are invested in these products and systems, as are immense human and material resources and financial assets. The resulting products and technologies must be secure against theft, piracy, and tampering to protect the wellbeing of patients, the commercial viability of medical technology businesses, and even the reliability of the medical sector as part of our society's critical infrastructure.

Secure, reliable, and trustworthy systems are nowhere more relevant than in the medical sector to make sure that patients' lives are not jeopardized. Certification and testing requirements are already in place, but are they enough? Prior to that stage, protection systems are necessary to defend the technology concept against all current and prospective threats and licensing solutions should be well planned to reap the monetary benefits through the sales channel. And with Al entering the game, the protections should include Machine Learning data training models and the derivative data.

With innovation and constant development part of the DNA of Wibu-Systems, we feel that we are in good company with the greatest medical pioneers who are devoting their lives to keeping or making people healthier and happier. Discover how our CodeMeter technology has already helped numerous vendors in the healthcare and life sciences field achieve these ambitions.

Yours.

Oliver Winzenried

CEO and Founder



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# **Protecting Software**

Ensure every software license for your medical device and life science application is genuine and purchased.

CodeMeter Protection Suite prevents software counterfeiting and reverse engineering by enacting authenticity mechanisms, guarding the integrity of the intellectual assets inherent in it, and securely encrypting entire programs or specific functionalities.



# Monetizing e-Health

Provide specialized healthcare services with a dynamic licensing approach.

CodeMeter License Central simplifies the process of creating, distributing, and managing licenses throughout the entire software's lifecycle, bolstered by an array of customercentric licensing models and seamless integration with mainstream ERP, CRM, and e-commerce platforms.



# **Safeguarding Medical Devices**

Apply familiar PC technology to the healthcare sphere.

The CodeMeter universe includes tamperproof hardware containers plugged or soldered to the PCB and specific software variants for embedded devices, adjustable in size for your field and designed to shield software and firmware downloads and upgrades from tampering.





Agfa HealthCare is one of the leading makers of diagnostic imaging equipment and the underlying healthcare IT systems for providers around the world. Its radiography systems are used both in high-end, specialized medical centers in leading economies and in less affluent markets or by smaller, independent providers.

Computed Radiography (CR) is a sophisticated, lifesaving, but also cost-intensive technology. Access to such systems can make a real difference for healthcare professionals and their patients.

# Agfa HealthCare and CodeMeter

The CR equipment made by Agfa HealthCare has been fitted with CodeMeter protections both to secure its proprietary operating systems and to facilitate broader access to the technology with a range of license models, including time-based licensing.





Operators can benefit from reduced entry prices with time-limited access to the imaging functions. Agfa HealthCare utilizes CodeMeter license management to offer subscriptions and pay-as-yougo options to its users to extend that service with more manageable payments. Everything is integrated in a simple online portal system to improve the user experience and bring high-end Computed Radiography to a wider audience, including the fast-growing healthcare markets in the global south.





The Med2Morrow system developed in Japan and marketed by BIC Medical is an innovative drug dispensing system that combines intricate mechanical engineering with sophisticated software to supply larger medical institutions with custom medicine packages for individual patients. The technology simplifies the lives of institutional pharmacists and ensures patient safety by taking the human factor out of the drug dispensing process.

With pharmacovigilance a crucial factor for safe healthcare provision, BIC Medical needed a solution to protect the operating software of its systems against tampering and monitor the dispensing operations with granular accuracy.

**BIC Medical and CodeMeter** 

CodeMeter was built into the Med2Morrow system to protect its sophisticated software with strong encryption and to add the means to monitor quantities and operating times for safer use and accurate billing. A choice of payment options

is given to operators, with payment either by usage time or by the number of pills processed by the system.

As Med2Morrow systems are operated offline for additional safety, BIC Medical chose CodeMeter hardware containers (CmDongles) to deliver the necessary licenses to the machines. The versatility of CodeMeter's license delivery options means that the license logistics could be integrated with the regular maintenance services for a smoother experience for the end user.









Dentsply Sirona provides high-end odontology equipment to dentists and orthodontists in the US, Europe, and Asia. Its groundbreaking CEREC system is a unique CAD/CAM system that can scan a patient's teeth and generate crowns, abutments, and veneers immediately onsite — no more temporary fillings and return visits to complete the procedure.

With the CEREC system developed as .NET software, particular care had to be taken to prevent reverse engineering and IP theft.

# **Dentsply Sirona and CodeMeter**

The .NET code behind the CEREC system is protected with CodeMeter's AxProtector tool's unique native .NET encryption capabilities and only decrypted during active use. The system keeps the precious IP safe from attackers with a minimal impact on performance, due to the flexible encryption system that lets developers encrypt only critical parts of their code.

Flexible licensing is possible with tiny CmStick/C dongles as containers, all thanks to the user-friendly CodeMeter License Central system. Licenses are easily activated and dispatched online to users in the field. Dentsply Sirona's specialized inLab software includes the ability to license individual modules, with the sales process fully integrated with Dentsply Sirona's internal systems for a smooth customer experience.







Fritz Stephan is a specialist maker of respirators and ventilation systems for neonatal, pediatric, and adult patients. Its systems are used both for in-patient and emergency response scenarios and are favored among users for their foolproof simplicity and reliability.

Behind the simple exterior lies sophisticated software and hardware with unique capabilities like its integrated turbine that produces air without access to separate oxygen supplies and smart sensors to monitor carbon monoxide build-up.

# **Fritz Stephan and CodeMeter**

For the EVE ventilation family, Fritz Stephan decided to bring Wibu-Systems on board to protect the software running their machines and to introduce new feature-based licensing. CmCards/SD and CodeMeter Embedded, the specialized runtime environment for embedded systems, are built into

the ventilators with their minimal hardware and software footprint to give access to CodeMeter's full license management capabilities.

Modular licensing was chosen to give access to additional functionalities. EVE systems are delivered with all ventilation functions included, but not all activated to reduce the unit price. At the point of need, operators can activate additional features like the EVENEO neonatal ventilation function for newborns. With the EVE line, Fritz Stephan and Wibu-Systems have realized the full potential of feature-based licensing.



# **Metrohm**



Metrohm is a premier Swiss maker of highly precise analytical instruments. Its ion analysis and titration analyzers are favored by lab technicians everywhere for their accuracy and user friendliness, now improved even further with the introduction of the OMNIS software.

The OMNIS system links up the diverse range of analytical systems made by Metrohm for a modular and easily automated process chain managed via a single PC application. Protecting this ingenious solution needed an encryption and licensing system that was just as versatile.

#### **Metrohm and CodeMeter**

CodeMeter is used to encrypt both the PC software and the embedded software running the Metrohm devices, using both hardware CmDongle and software CmActLicense containers in a single license management system. Metrohm benefits

from this flexibility, as only one system covers the entire protection needs and only one version of its OMNIS software needs to be certified for use.

For users, this adds further versatility, as they can flexibly add new devices or functions to their OMNIS setup once they have the full package installed. Metrohm engineers can easily activate new functions and licenses in the field, including trial and emergency licenses. Everything is accessible in a single portal, fully integrated with Metrohm's back office systems, for managing licenses, billing, and support services.















#### CodeMeter Certificate Vault

Certificates are used to authenticate and identify users or devices on the Internet, in emails, machine-to-machine communication, and elsewhere. CodeMeter Certificate Vault provides a secure means to store X.509 certificates on CodeMeter hardware and make them available via standard interfaces. This white paper delves into the guiding principles and challenges of secure certificate storage and the technology and use cases for CodeMeter Certificate Vault.



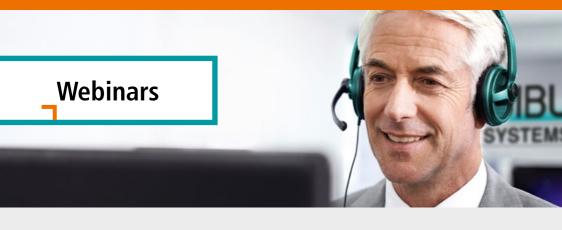
## **Electronic License Delivery**

With dedicated activation codes and security hardware dongles protecting premium applications against illegal use, the next step in the process is to identify the solution that streamlines administration and logistics of all the license models the ISV has generated. CodeMeter License Central is the fully featured, highly scalable, web-interface based license management system that integrates with your existing business process.



# **Integrity Protection for Embedded Systems**

Industry 4.0 brings about an unprecedented phase of interconnectivity that opens up to new forms of attacks the original equipment manufacturers are subject to. The White Paper illustrates how a digital certificate chain of trust applied to bootloader, operating system, and real-time application and configuration data is the key to top security and software integrity protection for embedded systems.





# **Security and Protection for Machine Learning**

Machine learning is reliable — provided the AI algorithm that generates the trained model is sound and has not been tampered with. The IP you need to protect includes the training data set, the training setup, and the resulting trained model. With CodeMeter, you can encrypt the model to safeguard it against unauthorized use, copying, or espionage in both online and offline scenarios. Additionally, CodeMeter can encrypt and sign data to add an extra layer of security on top of anonymization or pseudonymization.



# **Subscriptions: Relationships built to last**

Subscriptions range somewhere between the holy grail and the gold standard for software management. They promise a steady stream of income to the vendors and an affordable access to software without steep upfront costs to the users. Technically speaking, licenses can be set to run as long as a cancellation of the plan occurs or renewed regularly. In the latter case, you should still take the necessary steps and decide whether the renewal should be triggered automatically or by an ERP system or online store, or plan ahead for a multichannel sales of time contingents.



#### **Unleash the Power of CodeMeter**

The new generation of CodeMeter is a goldmine of opportunities for ISVs and their users. Supercharged with advanced protection mechanisms, licensing automation, and even more flexibility, the secure distribution of software is entering a new phase: Core features, integration in software applications, and complete support for back office processes have all been supplemented with unique functionalities for the world market.

Wibu-Systems is an innovative technology leader in the global software license lifecycle management market. In its mission to deliver the most secure, unique, and versatile technology to traditional software publishers and medical device makers, Wibu-Systems has developed a comprehensive, award-winning suite of hardware and software solutions with multipurpose, multiplatform, and multi-secure-element support that protects the integrity of digital assets, technical know-how, and IP against piracy, reverse engineering, tampering, sabotage, and cyberattacks. Its flagship CodeMeter® technology encrypts software, firmware, and sensitive data; the associated licenses are bound to secure elements including industry-grade mobile hardware (USB dongles, secure memory cards, ASICs) or soft containers that store digital fingerprints of the endpoint device. CodeMeter also facilitates software monetization with a multitude of predefined license models that enable new customer-centric business schemes, integrating seamlessly with existing back-office processes, such as ERP, CRM, and e-commerce platforms.











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