PHILIPS

Philips and cybersecurity

Committed to proactively addressing our customers’ security and privacy concerns

Position paper | January 2023

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The digitalization of healthcare – opportunities and threats

Today's healthcare systems are faced with the challenge of an aging population and the rising incidence of chronic diseases, and healthcare is struggling to develop appropriate and affordable care models. COVID-19 has greatly exacerbated these difficulties. Connected healthcare – enabled by devices, health apps, and platforms – has unprecedented potential to transform healthcare and enable better health and better care at a lower cost.

The proliferation of millions of connected digital devices allows users and networks to share, search, navigate, manage, compare and analyze a virtually limitless flow of data that can be used to enhance care outcomes.

This digital 'ecosystem' has already helped the industry expand the personal and healthcare-oriented smart devices portfolio, sparked innovation, and increased service efficiency.

For example, analysis of electronic medical records and diagnostic information gathered by imaging equipment, monitors, and handheld personal devices enhances the decision-making powers of professionals and enables people to take a more active role in managing their health.

However, the exponential increase in the volume and types of data available also leads to increased vulnerability to cybercrime. Healthcare data is the top target for cybercriminals and is 10 times more valuable than credit card data alone.[1]

Personal data in healthcare records is most valuable, as it can be used, for example, for malicious purposes, such as creating false identities or making false insurance claims.

Threats to healthcare institutions include malicious security attacks via viruses, worms, and hacker intrusions. Perpetrators range from attic-room hackers to organized crime and even nation-states.

The global, exponential rise of ransomware attacks all around us shows that even the largest and most sophisticated organizations can be vulnerable to disruption. In this case, some hospitals have had to divert patients to other clinics.

And now, the remote working and e-commerce that increased massively during COVID-19 appears to be here to stay. That brings about a host of new cyber challenges.

> "Security is job zero."
>
> **Shez Partovi**
> Chief Innovation & Strategy Officer, Philips

Philips' position on cybersecurity

Philips delivers innovations that help consumers and health professionals connect more easily and make better-informed decisions. Some of the most powerful and promising opportunities for these innovations involve research into large study groups and big data sets.

This is why security is a priority for Philips. And why every quarter, it features as a topic on the company's Executive Committee agenda via the Security Steering Committee (SSC). The goal of the SSC is to establish priorities and set the risk appetite for the Security domain, based on recommendations of Group Security, audit findings, and other appropriate inputs. Philips' strategic and competitive position relies heavily on data, digital innovation, and consumer trust.

Recognizing the concerns of our customers and consumers, and the critical role security plays across today's interconnected digital ecosystems, Philips is committed to the deployment of a comprehensive security strategy that assures the safety of product, business (enterprise information) and personal (patient) data.

Our security strategy encompasses our people, processes and technology, with the goal of ensuring the confidentiality, integrity and availability of critical data and the systems that house that data.

Security Designed In (in the EU, Security By Design) means taking an integrated approach so that systems and all their components are created from the start with security in mind. It is a key to keeping health information and medical devices protected and secure throughout their entire lifecycle.

Security – like safety and quality – is a prerequisite for confidence in the Philips brand. Customers and consumers must be able to rely on the security, safety and quality of our products and services. Therefore, we continue to be proactive in highlighting the benefits of connected health technology and continue to invest in secure systems that customers can rely on.

> "We must continue to live up to our customers' expectations of having state-of-the-art security in our products and services."
>
> **Gal Gnainsky**
> Chief Security Officer, Philips

Transparency, compliance, and beyond

Philips implements security within a heavily regulated medical device industry. Regulatory agencies such as the US Food and Drug Administration (FDA) require that hardware and software releases and changes be subjected to rigorous verification and validation methods to assure that high standards of safety, security, efficacy, quality, and performance are met in all applicable Philips products and services.

We handle all personal data with integrity, in compliance with all applicable privacy regulations of the countries in which we operate.

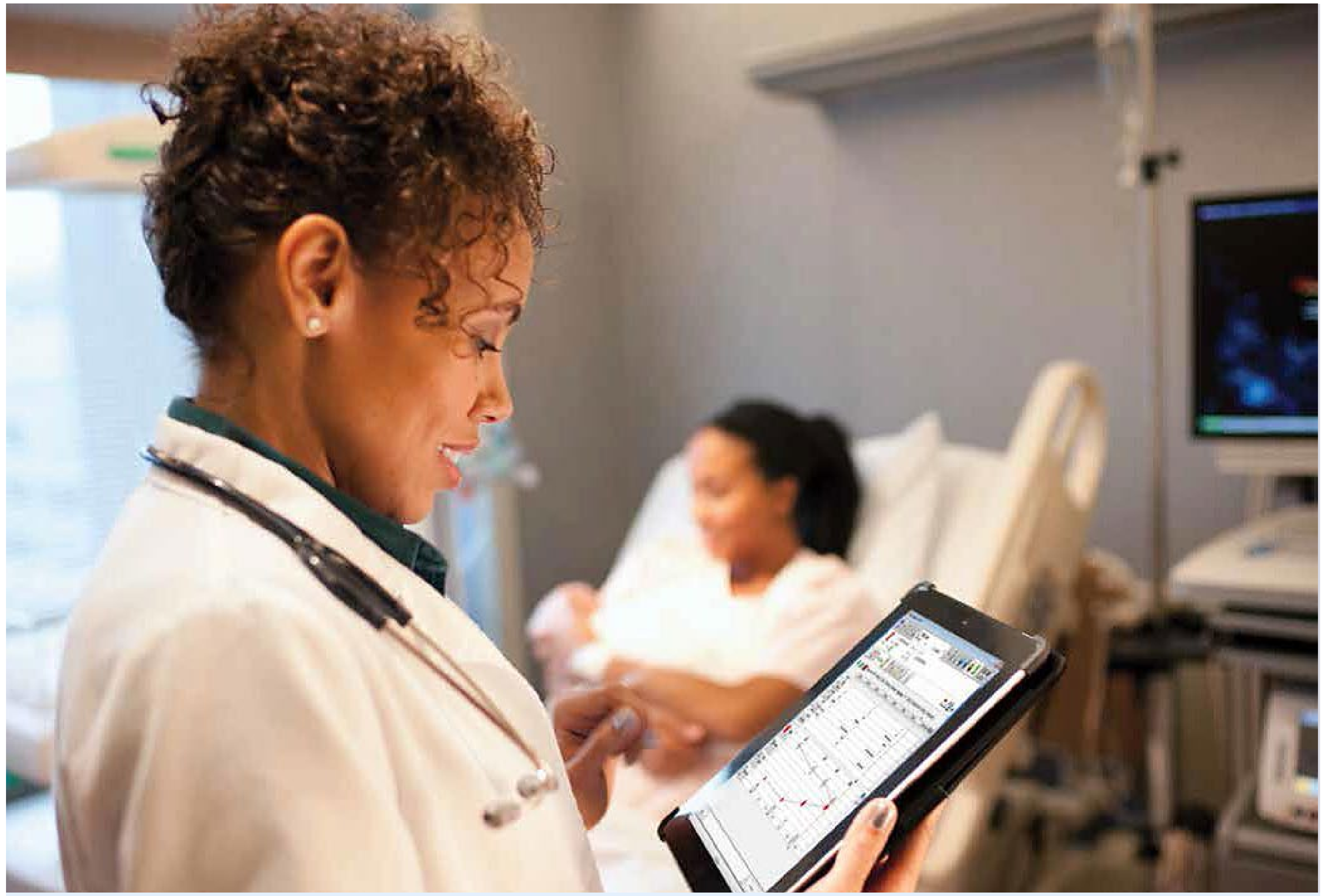
Philips strives to be open and transparent in reporting and remediating vulnerabilities and has developed a robust Coordinated Vulnerability Disclosure process.

Our strategy involves staying on top of emerging security vulnerabilities and potential external threats, and collaborating with regulatory agencies, industry partners, and healthcare providers, among others, to close security loopholes and implement safeguards.

Philips actively participates in key industry groups that have a security or privacy focus to align our efforts further. We strive to ensure that the appropriate and necessary customer security requirements are included in industry standards, guidelines, and initiatives.

We were a charter member of the US Dept. of Health and Human Services (HHS) Cybersecurity Taskforce that delivered a report illustrating the urgency and complexity of cybersecurity risks facing the healthcare industry, an effort that continues to influence industry working groups. We are strongly involved in the development of healthcare security standards through several standards development organizations, e.g., International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC).

Philips supports the World Economic Forum's 'Recommendations for Public-Private Partnership against Cybercrime'.



"By partnering with our customers and being transparent, we keep evolving the security of our products and services, with the goal of ensuring patient safety."

Dirk de Wit
Head of Product Security, Philips

Product security

Philips takes the growing risk of cybersecurity threats to our products very seriously. We have long been committed to the ongoing effort to continuously improve our processes and systems to minimize the risk to the patients who depend on our solutions and services.

We are keenly aware of the growing trend of sophisticated cyberattacks across industries and increasingly in healthcare. As hospital networks, clinical databases, medical devices, and personal health monitoring systems become more integrated, the potential for cybersecurity vulnerabilities also grows.

Philips was an early leader in recognizing that effective cybersecurity is no longer about protecting the 'box' or an individual product, and it requires a systematic approach that considers where and how devices are employed.

Philips Product Security governs the embedding of security into all products and services during the entire lifecycle, through a Product Security Framework – part of the Philips Excellence Framework. The security framework includes Product Security Risk Assessments, project-independent vulnerability and penetration assessments, specialized product security trainings, and response activities for vulnerabilities identified in existing products and services that are under maintenance and support contracts.

At Philips, Security Designed In is an end-to-end mindset: infusing security principles begins with product design and development through testing and deployment – followed up with robust policies and procedures for monitoring, effective updates, and incident response management.

To make our products and services robust against cyber threats requires an unwavering commitment to risk assessment, and adherence to security-based product development. It requires the fast deployment of security enabling technologies (such as encryption and patch management) and continuous improvement. That is why we have chartered our Product and Solutions Security Program to create, implement and update comprehensive and practical approaches to meet customer requirements.

Key Philips product security initiatives include:

Launch of an industry-advanced Philips Product Security Policy, consisting of policies, procedures, and standards empowering the organization to implement security best practices.

The policy outlines our strategic organization and procedures for:

- Maintaining a global network of security and privacy professionals.
- Developing and deploying best practices for our products and services.
- Guiding risk assessment activities related to vulnerabilities, as well as potential security and privacy threats.
- Guiding incident response activities related to identified security and privacy threats.
- Governing security embedded in products and services during their lifecycle
- Supporting our HealthSuite platform to align to the latest security standards for cloud environments.
- Continuously monitoring for vulnerabilities and validating fixes as part of our Secure Product Development Lifecycle – activities that are supported by our internal Security Center of Excellence.

Implementation of security standards that meet or exceed current regulatory requirements and industry best practices, including:

- Product security requirements for products and services that are not only aligned with regulatory recommended standards, but even used as the basis for the 80001-2-2 standard.
- Services security aligned with recognized standards such as NIST SP 800-53, ISO/IEC 27000 series, and HITRUST.
- Creation of customer-facing information, such as the industry-standard Manufacturer Disclosure Statement for Medical Device Security (MDS^2).
- Support for FDA, European Medical Device Regulation (MDR) and other national guidance that addresses cybersecurity in medical devices.

Philips' Security Center of Excellence shares information with leading cybersecurity researchers and test facilities around the world, assisting them to rapidly eliminate, reduce, and mitigate cyber threats.

In support of the successful Philips firm registration for the security option of IEC 62304, UL performed a comprehensive audit of the Philips Security Center of Excellence. The audit reviewed and verified core Philips Security Center of Excellence product security processes, including security risk management and risk control measures, software security verification planning, change management and continuous improvement, and the center's laboratory quality management system.

Monitoring and response to threats, vulnerabilities and security incidents

- Philips continually monitors for new security threats, vulnerabilities, and security incidents, including vulnerabilities identified by the operating system and by third-party software vendors, customers, and security researchers.
- Philips Product Security Incident Response Teams evaluate potential security incidents and vulnerabilities and develop response plans as necessary.

Malware protection and patch management

- Products that support commercially available malware protection may be delivered with pre-installed malware protection software or customer documentation, detailing product-specific Philips- approved malware protection parameters.
- Philips products might use third-party software, including operating systems such as Microsoft Windows and Linux. Impact assessments of their hotfixes by Philips product engineering teams typically begin within 48 hours of Philips' awareness of a new security vulnerability or patch availability.
- Philips launched the Cybersafe program to address the lifecycle cybersecurity risk, including a range of services that guard against lifecycle threats that come with obsolescence of platforms and devices.

A Coordinated Vulnerability Disclosure (CVD) to report and address identified vulnerabilities

- We have designed and implemented a CVD, which has been singled out as a best practice in the industry.
- Our CVD policy is publicly accessible, with clear communications channels for customers, researchers, and other security community stakeholders.
- The policy encompasses monitoring of and response to inbound communications, follow-up engagement, evaluation of vulnerability notifications and status tracking, and alignment with incident response, remediation, and prevention policies.

Philips is committed to continuing to innovate long-term strategic and effective measures to further instill the commitment to medical device product security.

We look forward to continuing this critically important conversation, in order to help meet our goal of improving billions of lives worldwide.

Enterprise information security

Philips' growth is fueled by innovative technology that our customers have grown to trust and rely upon. Sophisticated internal information systems support the design, development, and production of this technology.

Faced with the rapidly growing cybersecurity threat, which targets such technologies and the data housed within, the goal of the Philips information security organization is to safeguard enterprise information systems to ensure:

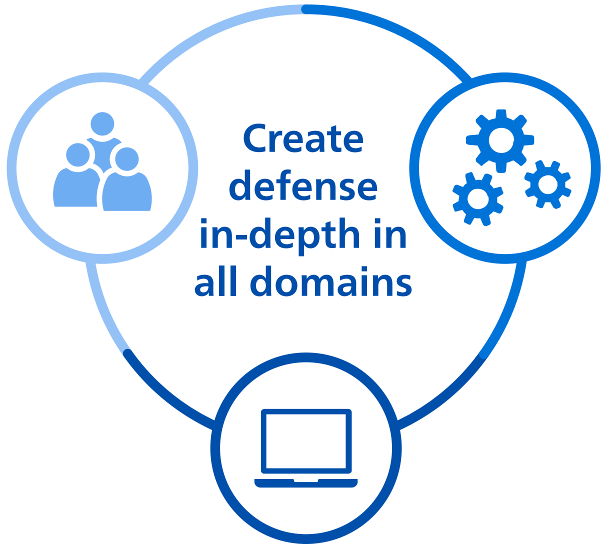
- **Our customers' trust**: enhance the Philips brand to be synonymous with safety, quality, and security
- **Our ability to grow**: prevent the loss of proprietary information to ensure the company's long-term competitive future
- **Our financial performance**: protect enterprise assets to prevent negative financial impacts, including loss of customers, revenue, and profit
- **Our operational stability**: maintain continuous operation by preventing the degradation or disruption of vital infrastructure
- **Our compliance to regulations**: ensure information systems comply with or exceed all regulatory requirements

Information security cannot be solved through technology alone. Comprehensive information security requires focus on three domains: people, processes, and technology. The Philips Information Security organization implements controls across these three domains to facilitate the following:

- **Confidentiality**: only those who should have access can retrieve data
- **Integrity**: information cannot be modified without detection
- **Availability**: information can be accessed when needed

Philips is meeting – and will continue to meet – the challenges of an evolving threat landscape to secure enterprise information systems and increase customer trust. The Philips Information Security organization will continue to focus investments on retaining top-tier cybersecurity talent, enhancing cybersecurity tooling and capabilities, and integrating security best practices in everything we do.

Information security focus on people, processes and technology



People

Focuses on the behavioral aspects of employees and improving their security aptitude, thereby developing a security culture

Processes

Focuses on our business processes and ensures security risk is evaluated, and proper mitigation steps are integrated into the process to reduce that risk

Technology

Focuses on understanding and monitoring our technology landscape and making technological improvements to enhance our security risk posture

> "Digitization allows us to connect our products and services to Philips' enterprise systems and subsequently to those of our suppliers and partners, for a seamless flow of information."

Stef Hoffman
Head of Information Security, Philips

Privacy

At Philips we have a longstanding commitment to respect the privacy of our customers, consumers, and other individuals we interact with, such as patients. Being transparent about how we address personal data helps to build trust. As we transform into a digital company, complying with our privacy standards is increasingly important to achieve that commitment. To this end, we have adopted our three Data Principles, one of which relates to privacy.

With our focus on health technology, data privacy and security have become strategically vital, as health data is among the most sensitive types of personal data. Our competitive position relies heavily on the use of this data, and public trust is paramount. Our commitment to privacy is enshrined in our Data Principles. Through these principles, we commit to handling all personal data with integrity in compliance with all applicable privacy regulations of the countries in which we operate.

Privacy and data protection are an integral part of our General Business Principles whereby we commit to:

- Implementation of Binding Corporate Rules (BCRs), known as the Philips Privacy Rules, that provide a baseline for privacy protection within Philips worldwide and allow international data transfer between Philips group companies
- Implementation of a privacy program and governance structure that embeds privacy and data protection in the company
- Limiting the collection of personal data to what is strictly necessary
- Informing individuals about the processing of their personal data
- Ensuring individuals can exercise their data-subject rights globally
- Taking appropriate steps to ensure the data is accurate and up to date
- Protecting personal data using appropriate security safeguards

As a global company, Philips needs to take into account all national privacy and data protection laws. Our BCRs and privacy program aims to ensure privacy compliance within Philips worldwide, including where privacy laws are absent.

As reflected in our BCRs, suppliers that process personal data on behalf of Philips must also agree to comply with stringent requirements.

Philips is committed to high security standards and responsible data stewardship through the principles of ‘privacy by design’. This approach embeds privacy and data protection controls throughout the entire data lifecycle, from the early design stage to deployment, collection, use, and, ultimately, data disposition and disposal.

To drive the advances in healthcare made possible by big data, we must foster trust and explain the value to the individual. We need to ensure the fundamental right to privacy and data protection is upheld. Through our commitment to high security standards and responsible data stewardship we can decrease fear and doubt, and offer even greater value to consumers through ongoing innovation.

More information

Philips security information ›

Privacy at Philips ›

Philips cybersecurity protection and upgrade services ›

Appendix:

Product Security Statement

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Product Security Statement

This paper summarizes the Philips position on securing our products, services, applications, and systems and describes our processes for providing products with Security Designed In.

Background

We at Philips recognize that the security of Philips healthcare, personal health, and home consumer products and services are an important part of your security planning. We are dedicated to helping you maintain the confidentiality, integrity, and availability of personal data, business data, and the Philips hardware and software products that create and manage this data.

Threats to the security of devices and personal and healthcare information continue to increase. These threats include malicious security attacks via viruses, worms, and hacker intrusions. Governments around the world have enacted legislation to criminalize many of these cyberattacks and to protect personal data (e.g., US HIPAA, Canada PIPEDA, EU GDPR, Japan PIPA, and others).

To fulfill our commitment to security, we at Philips maintain a global program to:

- Develop, deploy, and support advanced security features for our products and services.
- Manage security events in the field. Philips participates in industry and government collaborations to help ensure product innovations and clinical information is produced and available at the highest level of quality, availability, and confidentiality.

We implement security within a heavily regulated medical device industry and global climate. Government regulations (e.g., those of the US Food and Drug Administration (FDA), European Commission[2], UK digital security department[3], and the Chinese National Medical Products Administration) require that hardware and software changes be subjected to rigorous verification and validation to ensure high safety and performance standards are met in all Philips medical devices.

Likewise, Philips strives to ensure that same high standard for personal health products, home innovations, and services.

Organization

Philips operates under a global Product Security Policy governing Security Designed In creation of products and services. The policy also governs risk assessment, identification of vulnerabilities in existing products, and incident response activities. The Head of Product Security oversees the governance and compliance of this policy, reporting directly to the Philips Chief Security Officer. Under direction of the global Product Security Program, Philips has instituted and matured capabilities, including global monitoring, case escalation, rapid response, and full management visibility to security issues.

Digital revolution in healthcare

The connected ecosystem

The proliferation of millions of connected digital devices allows users and networks to share, search, navigate, manage, compare and analyze a virtually limitless data flow. This digital 'ecosystem' has sparked innovation, increased service efficiency, and helped the industry expand the portfolio of personal and healthcare-oriented smart devices. It has also dramatically escalated the potential of exposure to vulnerabilities and cyberattacks.

Interconnected, interoperable, and remotely controlled products and services in our industry are proliferating. Some areas that present as particularly vulnerable are:

- Provider networks
- Personal health devices
- Remote services
- Sensitive data storage
- Sensitive data on the move

The protection of customer networks and personal data within the ecosystem is of utmost importance.

To address this challenge, original equipment manufacturers (OEMs) such as Philips must take a strategic and integrated view of product security and establish a comprehensive risk-based cybersecurity program.

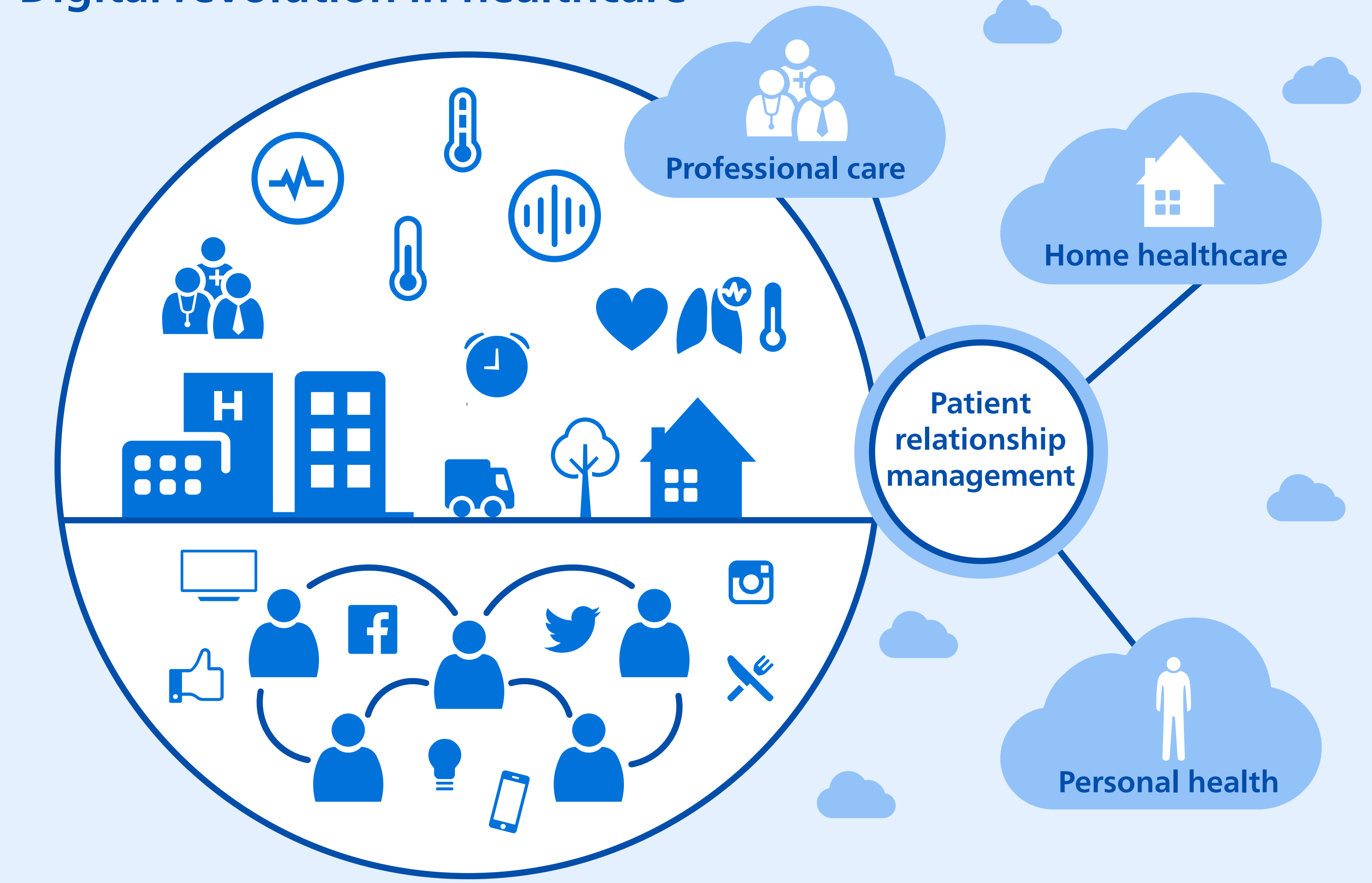
Internet of Things (IoT)

The Internet of Things (IoT) paradigm describes the pervasive interconnection and cooperation of smart things over the current and future Internet infrastructure. This revolution in data exchange empowers people to live healthier lives by using connected devices such as tablets, wearables, and handheld devices to control their health in a highly personalized manner. For example, Philips, in collaboration with partners in the industry, developed our HealthSuite Platform, which enables IoT devices and applications to operate in conjunction with deep sets of data. HealthSuite Platform offers a native cloud-based infrastructure and the core services needed to develop and run a new generation of connected, secure healthcare devices and applications.

Analysis of electronic medical records and diagnostic information gathered by imaging equipment, monitors, and handheld personal devices enhance professionals' decision-making powers and enable a more active role for patients to manage their personal health. These innovations are transforming not just the care of the chronically ill but also preventive care for those who want to remain healthy.

Next-generation mobile apps, services, and hardware that operate in this rapidly evolving environment will undergo rigorous risk analysis and security penetration testing. New devices will be protected with a secure defense framework that identifies users, authorizes consent, and tracks user activity to ensure data protection.

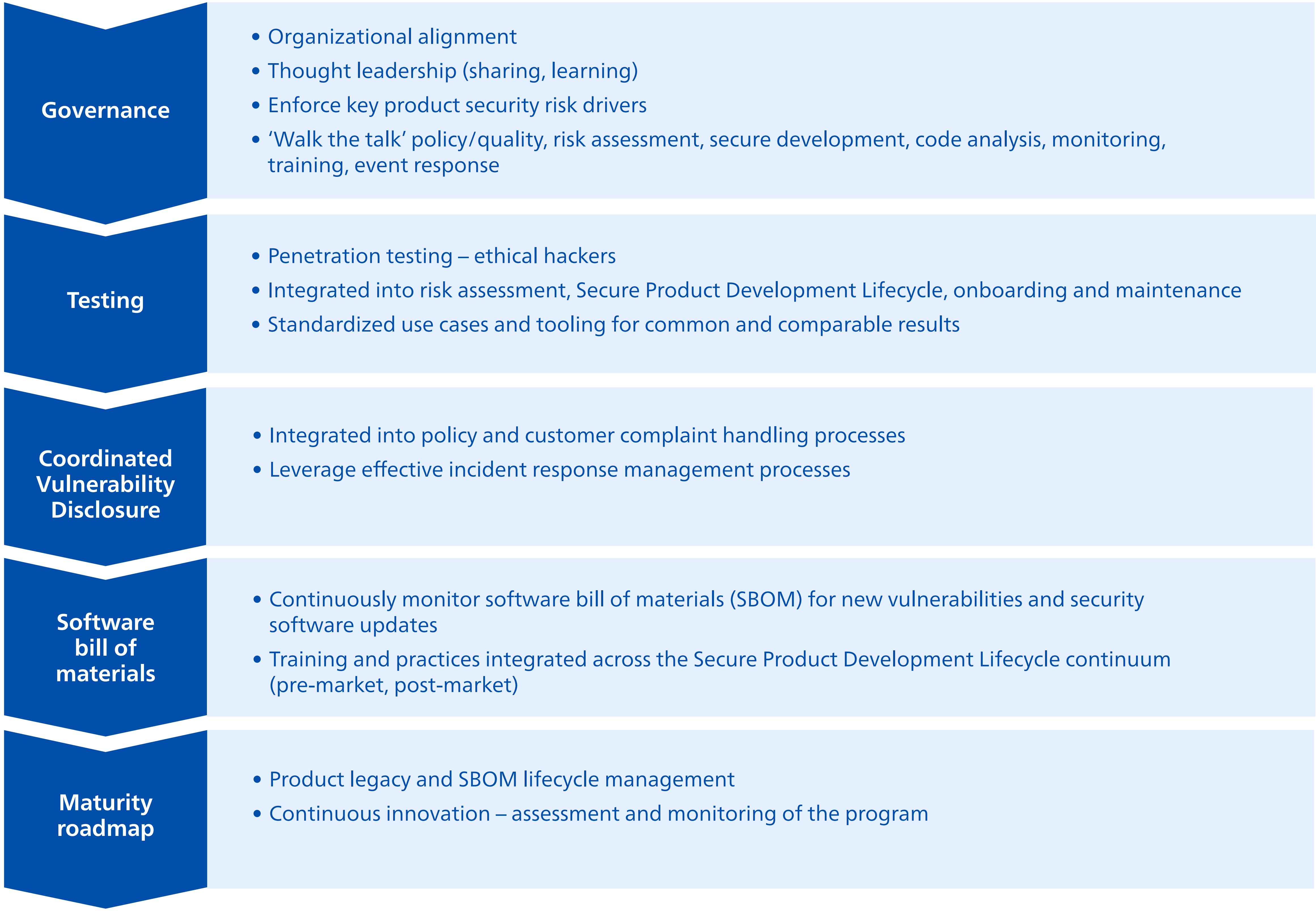
Digital revolution in healthcare



Key elements of the Philips Product Security Program

In a connected, interoperable healthcare ecosystem, the potential for exposure to vulnerabilities and attack is significant. This reality prompts Philips to devote extensive resources to mitigate such threats. Based on years of work as an industry leader in product security capabilities and product innovation, we suggest there are five essential components to a successful security program.

1. Governance
2. Testing
3. Coordinated Vulnerability Disclosure
4. Software bill of materials
5. Maturity roadmap



Governance

- Organizational alignment
- Thought leadership (sharing, learning)
- Enforce key product security risk drivers
- ‘Walk the talk’ policy/quality, risk assessment, secure development, code analysis, monitoring, training, event response

Testing

- Penetration testing – ethical hackers
- Integrated into risk assessment, Secure Product Development Lifecycle, onboarding and maintenance
- Standardized use cases and tooling for common and comparable results

Coordinated Vulnerability Disclosure

- Integrated into policy and customer complaint handling processes
- Leverage effective incident response management processes

Software bill of materials

- Continuously monitor software bill of materials (SBOM) for new vulnerabilities and security software updates
- Training and practices integrated across the Secure Product Development Lifecycle continuum (pre-market, post-market)

Maturity roadmap

- Product legacy and SBOM lifecycle management
- Continuous innovation – assessment and monitoring of the program

Governance

The alignment of Philips executive leadership secures the buy-in necessary to move forward successfully. Under their leadership, the dedicated in-house governance team provides continuous oversight, developing strategies and structure to successfully implement the critical attributes of the Product Security Program, including risk assessments, security testing, and incident management, as well as to manage and review policies, communications, stakeholder requirements, metrics, and a maturity roadmap for continuous improvement.

The team coordinates the efforts of external players across the cybersecurity ecosystem (customers, vendors, regulators, standards organizations, industry groups, and researchers, among others) through ongoing dialogue. This effort is highly productive in building key relationships and promoting industry best practices toward the safety and security of personal and medical devices. For example, Philips was one of two medical device manufacturers that participated in the US Health and Human Services (HHS) Cybersecurity Taskforce.

Governance of a comprehensive risk management strategy is core to the Philips Product Security Program and mission. That strategy includes holistic risk management process to prevent, mitigate, and/or remediate pre-market and post-market product security risks.

Philips emphasizes that consistent adoption of strategies to address key areas of assessed risk is essential to enable safe and secure products and services and to reduce potential exposures to data breaches, minimize third party vulnerabilities, and avoid sanctions from regulatory institutions and customers.

Testing

A medical devices manufacturer first, Philips has established a Security Center of Excellence (SCoE) to develop products that are 'cyber-resilient'. At the SCoE, a dedicated team of ethical hackers engages in continuous vulnerability and penetration testing to proactively identify product weaknesses. This complements the security testing done by the product engineering teams and is integrated in the Secure Product Development Lifecycle.

Philips product and services security testing covers a wide variety of cybersecurity tasks, including:

- Security vulnerability and penetration testing
- Product Security Risk Assessments
- Security source code analysis
- Third-party vendor engagements
- US Department of Defense technical product security testing
- Security training tailored to unique roles, including product architecture, development, and testing
- Tool validation
- Tool evaluation
- Threat monitoring
- Metrics for product development

Coordinated Vulnerability Disclosure (CVD)

The Coordinated Vulnerability Disclosure (CVD) Policy reassures customers that reasonable effort will be made to repair any vulnerabilities and prevent future damage.

It is important to handle all security incidents with a sense of urgency and sensitivity. A formal incident response management process has been implemented, which includes documenting all communication, opening a corrective action program, developing a solution, and authoring an incident report.

Confirmed vulnerabilities result in a direct report to government agencies, such as the US Department of Homeland Security Industrial Control Systems Cyber Emergency Response Team program, and are then communicated to the public. The US FDA pre- and post-market guidance on management of cybersecurity in medical devices (December 28, 2016) provides direction[4] on key principles that are globally applicable in practice and in cooperation with other governmental entities and processes. Transparency is key.

Philips was the first major medical device manufacturer to design and implement a CVD policy and remains today as a globally recognized industry leader with fully developed and operationally matured processes behind our policy.

When public media attention is drawn to security incidents, Philips is often singled out as a manufacturer that is prepared to address complex issues.

> "Philips was the only baby monitor manufacturer praised for responding to vulnerability warnings[5]."
>
> **Forbes**
>
> "We applaud Philips' commitment to fixing this vulnerability and their established protocol for handling incoming product vulnerabilities[6]."
>
> **ARS Technica**
>
> "Philips has been 'the most responsive' of all the companies in addressing the flaw[7]."
>
> **The Wall Street Journal**

Related: Monitoring and response to incidents and vulnerabilities

Software bill of materials (SBOM)

Companies (Philips included) reliant on the integration of third-party software open themselves to hidden risks posed by programming code that is not their own.

Creating a software bill of materials (SBOM) for every product is essential. This identifies and describes the open source and third-party software components and allows organizations to respond to possible security vulnerabilities or breaches quickly.

Philips is taking the industry lead to integrate an SBOM into every Philips Secure Product Development Lifecycle. We will implement processes and procedures to ensure the integrity of any software, firmware, or product developed for our customers.

Related: Philips open source governance and compliance program (governance of SBOM)

Maturity roadmap

Integrating product security into product development and consistently deploying product security processes across the portfolio sets the stage for manageable security throughout the lifecycle.
The purpose and intent of a maturity roadmap is to measure and improve Philips' processes and organizational capabilities. Ultimately our desire is to attain improved levels of product security maturity with new product introductions, ongoing service operations, and post-market lifecycle management.

As part of this effort, Philips is focused on a comprehensive product lifecycle management security strategy. It begins with an assessment and monitoring of installed base/legacy products to detect operating system obsolescence, incompatibilities, and hardware/firmware vulnerabilities. It also allows for ongoing, timely maintenance/updating and lifecycle scheduling.

Philips has also put in place a new Windows operating system policy, which ensures that in the future, for all systems in the installed base for which Philips guarantees support, customers have an option to get to a supported Windows operating system.

Philips product security in action

Product Security Risk Assessment and Security Designed In

Philips proactively conducts internal Product Security Risk Assessments. When weaknesses are identified, our engineering teams define configuration changes and re-engineering efforts that will harden the system against outside threats. The same information also drives security design requirements for new products, integrated into Philips secure development lifecycle processes for all products and services. The Philips Product Security Policy requires Security Designed In objectives as part of all new product creation efforts.

Monitoring and response to incidents and vulnerabilities

Philips Product engineering groups monitor new security vulnerabilities on an ongoing basis, including those identified by third-party software and operating system vendors and those reported from healthcare enterprises. A global network of Product Security Officers and their teams collect and manage information and address identified vulnerabilities that may affect Philips products and solutions.

When cyber attacks or other incidents are detected or reported, Philips Product Security Incident Response Teams evaluate each real or potential incident with an explicit threat/vulnerability/risk assessment, coordinate a unified response with teams across Philips, communicate status, and follow through to investigate and address security events in accordance with our Product Security Policy framework.

Philips Secure Product Development Lifecycle – Security Designed In

Industry trends have shown that cyber-attacks are moving to the application layer of products and pose a significant threat to customers and patient information over the Internet of Things. According to data collected by the Internet Storm Center, over 70% of attacks on networks are against the application layer. To strengthen the resiliency of our products and services, Philips strengthens our product realization process with capabilities, components, and techniques, including practices that align to standards such as ISO 27034, a practical and well-tested means of incorporating security and privacy in the software development process.

When leveraging this methodology, requirements and controls are addressed at each phase of the Secure Product Development Lifecycle, including the use of Product Security Risk Assessment, privacy compliance assessment (e.g., data privacy impact assessment) processes, privacy by design practices, static code analysis, third-party SBOM analysis, ethical penetration testing, and continuous product security training across the Philips organization. While tools and processes are key to the Philips Secure Product Development Lifecycle, Security Designed In is a mindset that requires an end-to-end approach that begins with architecture and high-level design, then progresses through to coding, testing, and post-market support.

Philips open source governance and compliance program (governance of SBOM)

Most software built today incorporates open source and other commercial off-the-shelf components. These third-party components may introduce vulnerabilities into a product to which the manufacturer is unaware. An SBOM carefully documents the tools used to build an application and identifies exactly what third-party components are included. This helps security organizations respond quickly and precisely to potential risks.

Many manufacturers do not have an accurate bill of materials listing for each of their products. With no accurate listing, they do not understand the vulnerabilities associated with the product components. When faced with a vulnerability issue without SBOM product information, there is no easy way to identify the affected code and introduce a solution. Hence, an agile response is exceedingly difficult.

The US president issued Executive Order 14028, Improving the Nation's Cybersecurity, to ensure the security of product software. Additionally, the executive order requires government agencies to obtain SBOMs for any new products they purchase. It also requires obtaining SBOMs for "any software, firmware, or products containing a third-party or open-source binary component."

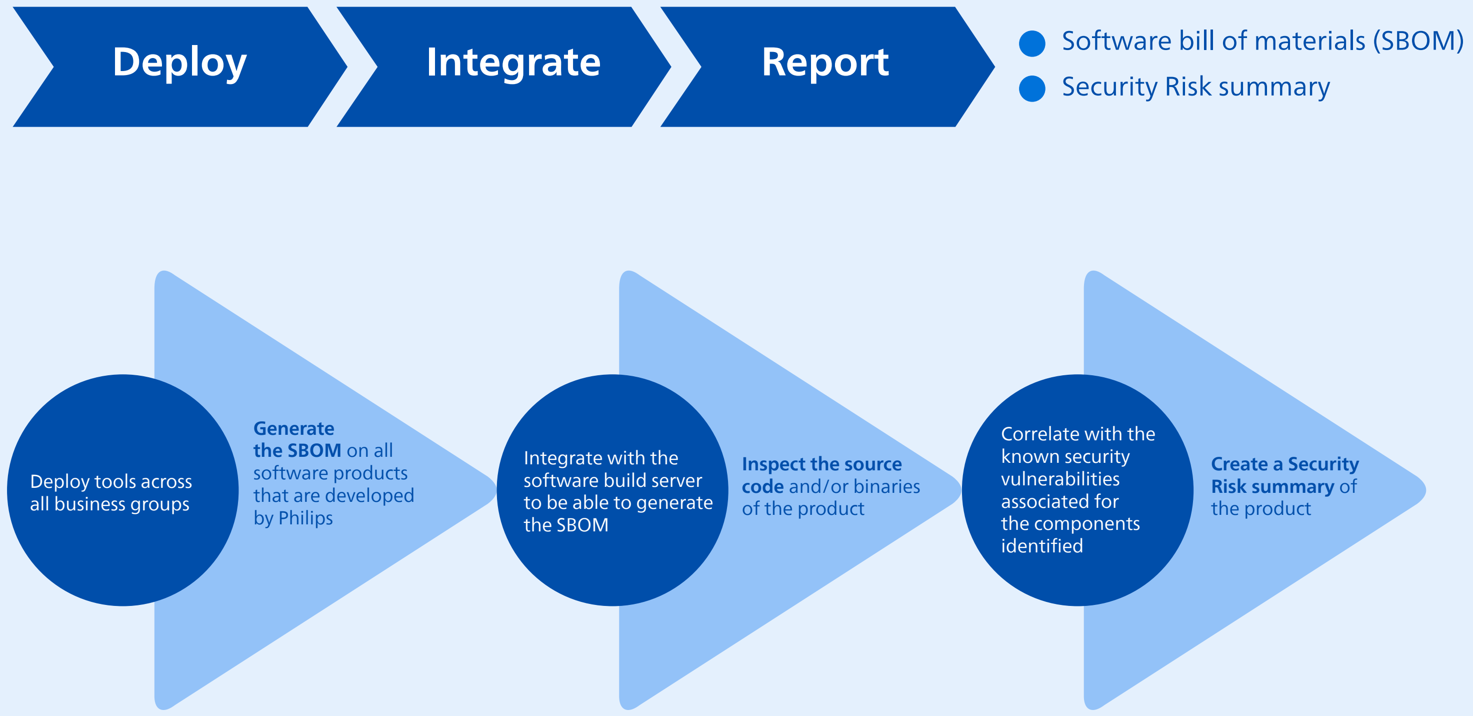
As a result of this new executive order, requirements are being adopted for the governance and disclosure of security vulnerabilities or defects for open-source and third-party software, such as those adopted by the US Veterans Administration and defined in the US National Institute of Standards and Technology Special Publication 800-53 (NIST SP 800-53).

NIST SP 800-53[8] is a US publication that recommends security controls for federal information systems and organizations, and documents security controls for all US federal information systems, except those designed for national security.

Philips is out in front of these requirements with our SBOM governance program, which includes three phases:

- **Deploy**: generate the SBOM on all software-driven products that are developed by Philips. This is being accomplished by deploying SBOM tools across all business groups.
- **Integrate**: integrate SBOM tooling and processes into the software development/build process. Inspect the source code and/or binaries of each product.
- **Report**: create a Security Risk summary of each product. Then correlate that summary with the known security vulnerabilities associated with identified components.

Approach to open source governance and compliance



● Software bill of materials (SBOM)

● Security Risk summary

Deploy tools across all business groups

Generate the SBOM on all software products that are developed by Philips

Integrate with the software build server to be able to generate the SBOM

Inspect the source code and/or binaries of the product

Correlate with the known security vulnerabilities associated for the components identified

Create a Security Risk summary of the product

Identifying and describing open-source and third-party software components within a product portfolio allows for quick response to potential security vulnerabilities/breaches. The following are seven key elements associated with a successful SBOM program:

1. Document SBOM requirements
2. Integrate SBOM into the Software Development Lifecycle process, including updating and maintenance
3. Identify SBOM vulnerabilities and license issues, and incorporate findings into Product Security Risk Assessments, then remediate as per the risks assessed
4. Include SBOM in all relevant product documentation
5. Monitor SBOM continuously for new vulnerabilities and security software updates
6. Update SBOM in relevant product documents and security risk assessments
7. Adjust overarching SBOM requirements as necessary based on changes in government regulation

The Philips Product Security SBOM process will be integrated into the System Development Lifecycle for each of our products in accordance with the Philips Product Security Policy. New systems will meet these expectations and be prepared for future upgrades. Legacy systems with security issues will be addressed with upgrades, network mitigations, or replacement.

Operating systems and patch management

Some Philips products use third-party commercial computer operating systems (OS), such as Microsoft Windows. We continually monitor relevant vendor and industry/media security announcements and perform risk assessments on medical devices affected by newly discovered vulnerabilities.

Microsoft releases information on Windows security patches (hotfixes) on a regular basis. Impact assessments of these hotfixes by Philips' product engineering teams typically begin within 48 hours of Philips' awareness of a new security vulnerability or patch availability. Following an assessment, an indication of Philips' response for affected products is available to users typically within five to 12 business days.

Depending on the nature of the threat and the affected product in question, a validated 'fix' or software update may be released. If the recommended response requires a change to the system software of a medical device, a software update may be released. Information concerning the availability and applicability of such updates is likewise available via Philips' standard service channels and, for some products, can be found via our website.

To provide you with this important information in a timely and convenient manner, the Philips Product Security webpage features access to Security Bulletins, FAQs, industry resources, white papers, and regularly updated product-specific vulnerability information. This information is formatted into simple, product-specific tables listing known software vulnerabilities and their current status, recommended customer action, and general comments. If you have any questions regarding the vulnerability tables, patch management, or other product security interests, contact Philips by email, productsecurity@philips.com, or contact your Philips Field Service Engineer.

Philips addresses the risk of an obsolete OS by providing an array of solutions based on the product. Products can be upgraded to the latest OS or replaced by more recent products (depending on the age of the product). Or, additional security measures can be provided, such as network isolation or whitelisting, to mitigate the risk.

Malware protection

To deploy and maintain the effective operation of your equipment, Philips products are delivered to operate within compliance of the system and security specifications, including device configuration, network, operating system, and/or software requirements for malware protection.

Please refer to your specific product documentation or instructions for more information.

Medical device MDS^2 forms

To assist our customers in meeting their obligations for security of patient health information, Philips has taken the lead in publishing product security information and has taken many steps to enhance the security of our medical devices in response to customer requests. When used properly, the security features of Philips healthcare products make it easier for users to meet their obligations to ensure the confidentiality, integrity, and availability of patients' health information. In light of the increased focus on medical device security and compliance with the patient-information security standards, the Healthcare Information and Management Systems Society (HIMSS) created a standard Manufacturer Disclosure Statement for Medical Device Security (MDS^2). The MDS^2 is intended to supply healthcare providers with important information that can assist them in assessing and managing the vulnerabilities and risks associated with electronic protected health information (ePHI) created, transmitted, or maintained by medical devices. Philips is aligned to the latest version (2019) of the MDS^2 template.

Philips customers can sign in to the InCenter to access MDS^2 forms.

Customer role in product security partnership

We recognize that the security of Philips products needs to be an important part of your security-in-depth strategy. However, protection can only be realized if you implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from internal and external threats. Following industry-standard practice, your strategy should address physical security, operational security, procedural security, risk management, security policies, and contingency planning. The practical implementation of technical security elements varies by site and may employ a number of technologies, configurations, and software solutions. As with any computer-based system, protection can include firewalls, network segmentation, and/or other security devices between the medical system and your institution's network. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy. Any device connection to an internal or external network should be made with appropriate risk management for product effectiveness and data and systems security.

Policies on third-party software and patching

Philips sells highly complex medical and personal devices and systems. Only Philips-authorized changes are to be made to these systems, either by Philips personnel or under Philips' explicit, published direction. With the current rise in security threats, Philips product engineering groups work to qualify security-related third-party software and solutions for selected equipment.

Moreover, we continue to treat patient and operator safety as our primary concern. We are required to follow regulatory and quality assurance procedures to verify and validate modifications to our medical devices. As with other medical devices, any 'software only' Philips products should be used only on computers and networks that are properly secured in accordance with your Philips product documentation, service agreements, and instructions for use. We strongly suggest that your security staff monitor system and application vulnerabilities and keep the operating system and other installed software running on your system patched and up-to-date.

Philips sells a broad range of devices: lifestyle products and home monitoring systems; image acquisition and viewing systems; IT-oriented picture archiving and communication systems (PACS); 24/7 life-critical systems; and real-time patient monitors. The diverse nature of our product portfolio has led us to support a wide range of solutions, including the installation and maintenance of third-party software on our systems. Please contact Philips for more specific information on your particular product.

General case

Most Philips equipment does not permit third-party software installation of any kind by the customer (e.g., anti-virus scanners, office productivity tools, system patches or on-platform firewalls) unless documented by Philips as an operating specification requirement – or prior written consent is attained. Unauthorized modifications to Philips products could void your warranty and alter the regulatory status of the device. Any resulting service required from unauthorized modification is not covered under our service agreements. Such unauthorized modifications can affect the performance or safety of your device in unpredictable ways. Philips is not responsible for equipment that has been subject to unauthorized modification.

When Philips authorizes the use of third-party software, system patches, or upgrades, the authorized installation is typically carried out by (1) Philips at the time of manufacture or installation, or (2) a post-installation Philips-qualified service engineer.

Exceptions
Philips may permit in certain circumstances the installation or enabling of third-party software directly by a Philips-qualified service engineer, but always under explicit published guidance of Philips and only to be applied to the particular system and version covered by the Philips written authorization.

Prior to considering the installation or enablement of any third-party software on a Philips product, you should contact your local Philips service representative to determine if your particular product has been qualified for that specific software and, if so, what restrictions may apply.

It is essential to understand that any unauthorized modification of a Philips medical device or system (e.g., product firewall changes, software patches, security software, utilities, games, music files or other software programs) can adversely affect system performance or safety in unpredictable ways, thereby depriving your staff and their patients of protections afforded by Philips, as well as risking compliance with regulatory and quality requirements. Possible detrimental side effects of these installations or modifications might include:

1. Opening or widening of pathways that allow a compromise of access or control
2. Introduction of viruses, spyware, Trojans, backdoor access, or other remote agents
3. Installation of unauthorized updates that could lead to product and system vulnerabilities

Should you suspect or know of any unauthorized modifications to your Philips product or solution, you should immediately report it to Philips Customer Services or your Philips Field Service Engineer, who will assist you in determining the appropriate action.

Philips Remote Services

The global, web-based Philips Remote Services (PRS) network connects many of your Philips systems to our advanced service resources. This state-of-the-art design provides your equipment with a single point-of-network access to on-site Philips equipment using Virtual Private Network technologies. This tunnel approach was developed to provide a best-in-class remote service solution that secures the connection through explicit authorization and authentication control with encryption of all of the information in the service session.

Philips product innovations and solutions in a changing world

In line with the need to increase security of our products, Philips continues to examine and re-engineer existing products to best accommodate the requirements of our security-minded customers. We are deeply engaged in creating the products of tomorrow based on fundamental security principles.

We will continue to work closely with providers, IT organizations, and consumers to provide flexible solutions to today's problems even as we create new Security Designed In products.

Thank you for your continued interest in the many innovative solutions provided by Philips.

1. Why Medical Records are 10 Times More Valuable Than Credit Card Info | CyberPolicy
2. The European Union Medical Device Regulation
3. UK Network and Information Systems Regulations
4. Postmarket Management of Cybersecurity in Medical Devices | US Food and Drug Administration
5. It's depressingly easy to spy on vulnerable baby monitors using just a browser | Forbes
6. 9 baby monitors wide open to hacks that expose users' most private moments | ARS Technica
7. Flaws in baby monitors open door for hackers | The Wall Street Journal
8. Security and Privacy Controls for Information Systems and Organizations | US National Institute of Standards and Technology

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