

Best Practices Guide for Medical Device Cybersecurity

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1 **Introduction**

In the rapidly evolving landscape of healthcare technology, the cybersecurity of medical devices has become a critical concern. As these devices become increasingly interconnected and software-dependent, they offer immense benefits to patient care but also present new vulnerabilities to cyber threats. Such vulnerabilities, if exploited, may result in patient harm, delays in treatment, etc.

This document is intended for medical device manufacturers and healthcare providers. It provides recommendations on cybersecurity best practices for medical devices, focusing on both pre-market and post-market stages of the device's total product lifecycle (TPLC).

The pre-market stage focuses on the development phase, where cybersecurity measures are integrated into the device during the development phase. This crucial stage encompasses designing security features (i.e. Secure by Design), developing risk management strategies, conducting thorough security testing, preparing user information and documentation, developing a post-market cybersecurity plan, and creating a Software Bill of Materials (SBOM).

The post-market stage addresses cybersecurity risks throughout the device's operational life. This stage is further divided into three sub-stages: the Support Stage, the Limited Support Stage, and the End of Support Stage. During the Support Stage, active maintenance and updates are provided to ensure the device remains secure against emerging threats. The Limited Support Stage involves reduced but continued security support, while the End of Support Stage focuses on managing cybersecurity risks for legacy devices that are no longer actively supported.

By adhering to these best practices across both premarket and post-market stages, manufacturers and healthcare providers can work together to enhance the security posture of medical devices, protect patient safety, and maintain the integrity of healthcare systems. As the field of medical device cybersecurity continues to evolve, it is crucial to stay informed about emerging threats and adapt the applicable strategies accordingly.

26 **2 Scope**

27 This document is not intended to provide information on regulatory requirements, but rather offers best practices
28 recommendations and considerations on medical device cybersecurity throughout the Total Product Life Cycle
29 (TPLC).

30
31 The scope of this document is to provide recommendations to all medical device manufacturers and healthcare
32 providers on general cybersecurity principles to ensure medical devices are secure throughout their lifecycle, from
33 device development to the end-of-support phase.

34 **3 Definitions**

35 **Asset:** physical or digital entity that has value to an individual, an organization or a government.

36
37 **Attack:** attempt to destroy, expose, alter, disable, steal or gain unauthorized access to or make unauthorized use
38 of an asset.

39
40 **Availability:** property of being accessible and usable on demand by an authorized entity.

41
42 **Confidentiality:** property that information is not made available or disclosed to unauthorized individuals, entities,
43 or processes.

44
45 **Cybersecurity:** a state where information and systems are protected from unauthorized activities, such as access,
46 use, disclosure, disruption, modification, or destruction to a degree that the related risks to confidentiality, integrity,
47 and availability are maintained at an acceptable level throughout the life cycle.

48
49 **End of Life (EOL):** Life cycle stage of a product starting when the manufacturer no longer sells the product beyond
50 their useful life as defined by the manufacturer and the product has gone through a formal EOL process including
51 notification to users.

52
53 **End of Support (EOS):** Life cycle stage of a product starting when the manufacturer terminates all service support
54 activities and service support does not extend beyond this point.

55
56 **Exploit:** defined way to breach the security of information systems through vulnerability.

57
58 **Integrity:** property whereby data has not been altered in an unauthorized manner since it was created, transmitted
59 or stored.

60
61 **Patient Harm:** physical injury or damage to the health of patients.

62
63 **Security testing:** type of testing conducted to evaluate the degree to which a test item, and associated data and
64 information, are protected so that unauthorized persons or systems cannot use, read, or modify them, and
65 authorized persons or systems are not denied access to them.

66
67 **Software Bill of Materials (SBOM):** list of one or more identified components, their relationships, and other
68 associated information.

69
70 **Threat:** potential for violation of security, which exists when there is a circumstance, capability, action, or event
71 that could breach security and cause harm.

72
73 **Total Product Life Cycle (TPLC):** Development, Support, Limited Support, and End of Support Stages in the life
74 of a medical device.

75
76 **Vulnerability:** weakness of an asset or control that can be exploited by one or more threats.

77 **4 General Principles**

78 **4.1 Shared Responsibilities**

79 The cybersecurity of medical devices is a shared responsibility between device manufacturers and healthcare
80 providers. Both parties need to understand their roles, responsibilities and collaborate closely with each other to
81 continuously monitor, assess, mitigate, communicate and respond to potential cybersecurity risks and threats
82 throughout the device's life cycle.

83
84 In addition, medical devices manufacturers are encouraged to take ownership of improving the security outcomes
85 and evolving devices accordingly. The burden of security should not fall solely on the healthcare providers.

86
87 Although technical subject matter expertise is crucial for device security, senior management in the manufacturers
88 and healthcare organizations are the primary decision-makers for implementing changes within an organization.
89 Hence, senior management plays an important role in ensuring the safety of the device during its life cycle.

90

91 **4.2 Transparency and Communication**

92 Cybersecurity information sharing is a foundational principle in the TPLC approach to ensuring the safety and
93 security of medical devices. Active participation, timely sharing of information and coordinated vulnerability
94 disclosure between the manufacturers and healthcare providers are the encouraged best practices.

95
96 The active engagement between the manufacturers and healthcare providers will increase the awareness and
97 allows for timely and appropriate planning at each stage of TPLC of the medical device. There should be
98 appropriate channels available to ensure the accessibility of the required information for the manufacturers and
99 healthcare providers.

100

101 **4.3 Secure by Design**

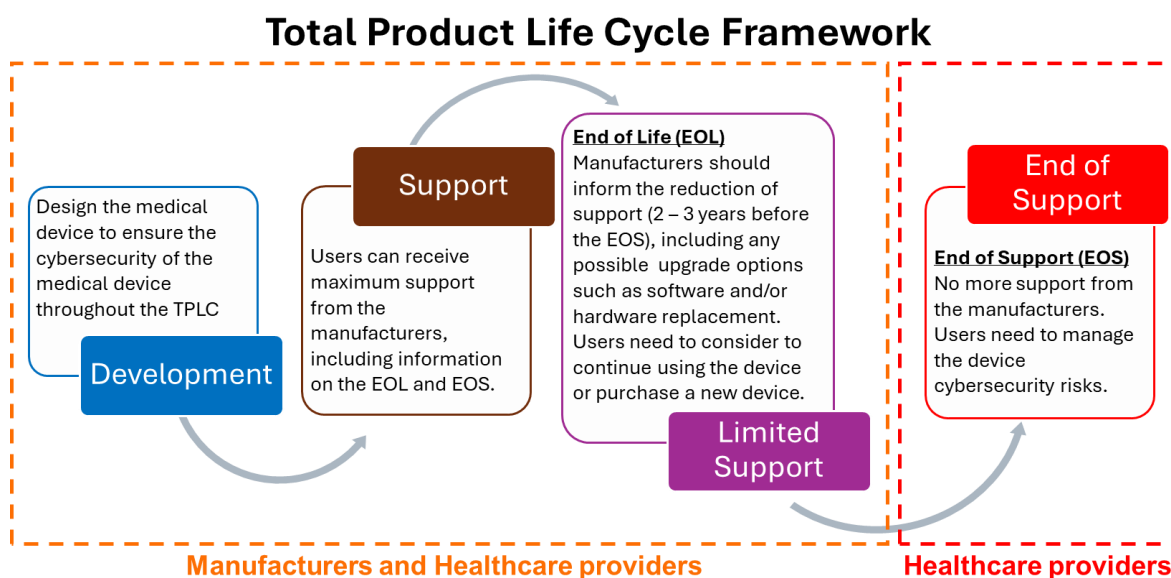
102 Secure by design is a fundamental principle in cybersecurity that emphasises building security into systems and
103 software at the development phase. This approach involves considering potential threats and vulnerabilities at
104 every stage of the development process, from initial planning to implementation and maintenance.

105
106 By integrating security measures into the core architecture and design of a medical device, it will result in a more
107 robust and resilient medical devices that are inherently resistant to cyberattacks. It will help to enhance the overall
108 security of the medical device during its life cycle and reduces the need for costly retrofitting and patch management
109 in the long run.

110 5 Overview of Total Product Life Cycle Framework (TPLC)

111 The risks associated with the cybersecurity threats and vulnerabilities need to be considered throughout the Total
 112 Product Life Cycle (TPLC) of the medical device. The TPLC approach will allow medical device manufacturers and
 113 healthcare providers to manage and adapt to the rapid changes of the medical devices. The aspects involved in
 114 TPLC include (but not limited to) design control, shared responsibilities between manufacturers and healthcare
 115 providers, risk management at each stage, etc.

116
 117 The TPLC consists of different stages, i.e. Development, Support, Limited Support and End of Support. It is crucial
 118 that risk management is applied at each stage of the TPLC of the medical device. The final two stages of TPLC
 119 signals the End of Life (EOL) and End of Support (EOS) for the medical devices. EOL refers to the end of the
 120 projected useful life of the medical device and thus only limited support from the manufacturer will be available. On
 121 the other hand, at the EOS stage, no further support should be expected from the manufacturer and thus the
 122 management and responsibility of the device should solely be performed by the healthcare providers. It is therefore
 123 crucial for both the manufacturers and healthcare providers to work together to ensure the medical device can be
 124 reasonably protected against the cybersecurity threats.
 125



126
 127
 128
 129 Figure 1: Total Product Life Cycle Framework

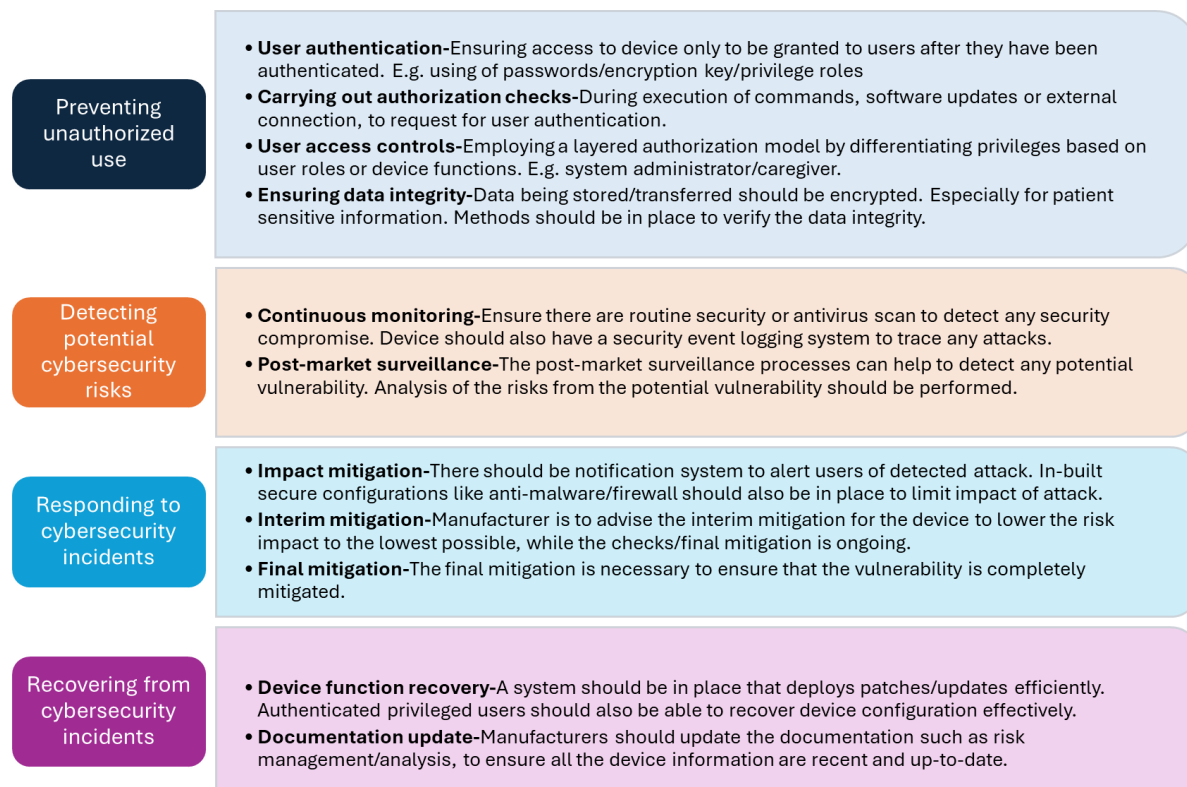
The cybersecurity considerations at each stage of TPLC will be discussed in more details in the following sections.

130 **6 Pre-market – Development stage**

131 It is important for medical devices manufacturers to prioritise medical device cybersecurity throughout the entire
 132 product life cycle. However, there are specific pre-market elements that should be considered during the
 133 development stage to ensure the security of the medical device throughout the TPLC. These include (i) Designing
 134 Security Features, (ii) Risk Management Strategies, (iii) Security Testing, (iv) User Information, and (v) Post-Market
 135 Plan. In addition to the above elements, manufacturers should consider preparing a Software Bill of Materials
 136 (SBOM) to allow both themselves and healthcare providers to have an oversight on the software components used
 137 in the device, thus enabling prompt assessment, identification and remediation of any potential vulnerabilities.
 138

139 **6.1 Designing Security Features**

140 **Designing Security Features** - Incorporating security features into the product design to mitigate potential
 141 vulnerabilities and threats. These are some possible design considerations:
 142



143 Figure 2: Design considerations for security features

144 **Secure by default** and **Secure by design** are two important principles that aim to enhance the security of systems
 145 and applications:
 146

- 147
- 148 a) Secure by default
 - 149 Secure by default refers to the principle of configuring systems and applications to be as secure as possible
 150 out of the box, without requiring additional user intervention. The main focus of secure by default is to ensure
 151 that the initial configuration of a system or application prioritises security, thereby reducing the risk of
 152 misconfiguration leading to security vulnerabilities. This approach aims to minimize the potential for oversight
 153 or human error in configuring security settings, thereby enhancing the overall security posture of the system.
 154
 - 155 b) Secure by design
 - 156 Secure by design refers to the approach of integrating security measures and considerations into the design
 157 and architecture of a system or application from the outset. The primary focus of secure by design is to
 158 proactively identify and address potential security vulnerabilities during the design phase, rather than as an
 159 afterthought. As a result, this creates systems that are inherently secure, reducing the likelihood of security
 160 breaches and the need for extensive retroactive security measures.
 161

162 Both principles are crucial for strengthening cybersecurity and mitigating potential risks. Hence, medical devices
 163 manufacturers are recommended to integrate both principles into the product design and development processes.
 164
 165

166 6.2 Risk Management Strategies

167 **Risk Management Strategies** - Applying accepted risk management strategies to identify, analyse, assess, and
 168 mitigate cybersecurity risks associated with the device. Here are some of the key strategies of the cybersecurity
 169 risk assessment and planning that medical device manufacturers and healthcare providers need to consider:

170 a) Risk Assessment

- 171 • **Identifying Assets** - The first step is to identify all the assets, including medical devices, software and
 172 data, that are part of the intended use environment.
- 173
- 174
- 175 • **Threat Identification** - Assess the potential threats and vulnerabilities that could impact the confidentiality,
 176 integrity, and availability of the medical devices and associated data.
- 177
- 178 • **Vulnerability Analysis** - Evaluate the vulnerabilities present in the devices, including outdated software,
 179 weak authentication mechanisms and potential points of entry for attackers.

180
 181 Vulnerability scoring is a method used to assess and quantify the severity and potential impact of security
 182 vulnerabilities in systems, applications, or devices. It provides a standardised way to prioritise and address
 183 vulnerabilities based on their characteristics and potential risk they pose to the device. There are several
 184 common vulnerability scoring systems used in the cybersecurity industry. Two of the most widely used
 185 are the **Common Vulnerability Scoring System (CVSS)** and the **Common Weakness Scoring System**
 186 **(CWSS)**.

- 187
- 188 • **Common Vulnerability Scoring System (CVSS):**
 189 CVSS provides a numerical score based on several metrics, including exploitability, impact, and
 190 complexity, to assess the severity of a vulnerability. The base score reflects the intrinsic qualities of a
 191 vulnerability and ranges from 0.0 to 10.0, with 10.0 being the most severe. CVSS also includes temporal
 192 and environmental scores to account for factors such as the availability of patches and the specific
 193 environment in which the vulnerability exists.

- 194
- 195 • **Common Weakness Scoring System (CWSS):**
 196 CWSS focuses on scoring the inherent weaknesses in software, rather than specific vulnerabilities. It aims
 197 to quantify the severity of common weaknesses that can lead to vulnerabilities. CWSS considers factors
 198 such as the prevalence of the weakness, the potential impact of exploitation, and the ease of detection
 199 and remediation. CWSS provides a numerical score to represent the severity of a weakness, allowing
 200 organizations to prioritise efforts to address common weaknesses in their software development
 201 processes.

202
 203 In addition to these standardized scoring systems, organizations may also develop their own internal
 204 vulnerability scoring methodologies tailored to their specific needs and risk profiles. These scoring
 205 systems often take into account organizational context, industry-specific threats and the potential impact
 206 of vulnerabilities on critical assets.

- 207
- 208 • **Impact Analysis** - Determine the potential impact of a cybersecurity breach on patient safety, data
 209 integrity, and healthcare operations. The manufacturers should have a process in place to assess the
 210 impact from the cybersecurity vulnerability. For example, manufacturers using a scoring system (e.g.
 211 CVSS and CWSS discussed above) to assess the vulnerability and thus determine the need for and
 212 urgency of the response.

213 b) Risk Management

214
 215 Risk analysis should prioritise evaluating the potential harm to patients/users by taking into account the
 216 following: 1) how easily the cybersecurity vulnerability can be exploited, and 2) the severity of patient harm if
 217 the vulnerability were to be exploited. Additionally, these analyses should consider compensating controls and
 218 risk mitigation strategies.

- 219
- 220
- 221 • **Risk Mitigation** - Develop strategies to mitigate identified risks, such as implementing security controls,
 222 patching vulnerabilities, and enhancing access controls.
- 223
- 224 • **Residual Risk Analysis** - Assess the remaining risks after implementing mitigation measures and
 225 determine if they are acceptable or if further action is required.
- 226
- 227 • **Risk Communication** - Communicate the identified risks with transparency and mitigation strategies to
 228 relevant stakeholders, including healthcare providers, device manufacturers and regulatory authorities.

229 c) Security Plan Development

- 231 • **Security Controls Implementation** - Develop and implement security controls to protect medical devices
232 and associated systems from cyber threats. This may include encryption, access controls, intrusion
233 detection systems, and secure software development practices.
- 234
- 235 • **Incident Response Planning** - Develop a comprehensive incident response plan to address
236 cybersecurity incidents, including procedures for detecting, responding to, and recovering from security
237 breaches.
- 238
- 239 • **Regulatory Compliance** - Ensure that the security plan aligns with relevant regulatory requirements or
240 other relevant regulatory bodies in different countries.
- 241
- 242 d) Continuous Monitoring and Improvement
- 243 • **Ongoing Assessment** - Continuously monitor the security posture of medical devices and associated
244 systems to identify new risks and vulnerabilities.
- 245
- 246 • **Security Training** - Provide training to healthcare staff on cybersecurity best practices and the safe use
247 of medical devices to minimize the risk of human error leading to security incidents.
- 248
- 249 • **Feedback Loop** - Establish an effective feedback loop to incorporate lessons learned from security
250 incidents and near-misses into the risk assessment and planning process.
- 251

252 On top of the recommended strategies above, the cybersecurity risk management process is complementary to
253 and can be integrated as part of ISO 14971 standard - Application of risk management process for medical devices.
254

255 **6.3 Security Testing**

256 **Security Testing** - Conducting thorough security testing to identify and address any potential weaknesses or
257 vulnerabilities in the device's security measures.
258

259 There are several types of cybersecurity testing that manufacturers can conduct to assess the security of their
260 systems and applications. Here are some common cybersecurity testing methods that can be considered:
261

- 262 a) Vulnerability Assessment
263 This involves scanning systems for known vulnerabilities and weaknesses, often using automated tools, to
264 identify potential entry points for attackers.
265
- 266 b) Penetration Testing (Pen Testing)
267 Penetration testing involves simulating real-world attacks on systems, networks, or applications to identify and
268 exploit vulnerabilities. This helps organizations understand their security posture and potential impact of
269 successful attacks.
270
- 271 c) Security Audits
272 Security audits involve comprehensive reviews of an organization's security policies, procedures, and technical
273 controls to ensure compliance with security standards (e.g. TR 67:2018, UL 2900-1, UL 2900-2-1) and best
274 practices.
275
- 276 d) Security Code Review
277 This involves manual or automated review of source code to identify security vulnerabilities, such as injection
278 flaws, authentication issues, and other weaknesses.
279
- 280 e) Security Configuration Review
281 This type of testing assesses the configuration settings of systems, networks, and applications to ensure that
282 they are aligned with security best practices and standards.
283
- 284 f) Security Awareness Training and Testing
285 This involves educating employees on periodic basis (e.g. monthly, bimonthly or quarterly) about security best
286 practices and conducting simulated phishing attacks or other tests to assess their awareness and response to
287 potential security threats.
288
- 289 g) Red Team vs. Blue Team Exercises
290 Red team exercises involve simulating real-world attacks to test an organization's defences, while blue team
291 exercises involve defenders responding to and mitigating these simulated attacks.
292
- 293 h) Incident Response Testing
294 This involves simulating security incidents to test an organization's incident response capabilities, including
295 detection, containment, eradication, and recovery.
296

297 These are just a few examples of cybersecurity testing methods that organizations can use to assess and improve
298 their security posture. There is no one size fit all testing method. Each type of testing serves a specific purpose in
299 identifying and addressing security vulnerabilities and threats. Organizations can adopt the best-fit testing methods
300 or combination of testing methods that is tailored to their specific needs.
301

302 **6.4 User Information**

303 **User Information** - Providing comprehensive and user-friendly information to guide users on how to operate the
304 device securely and effectively.

305
306 Some recommendations for this documentation should include:
307

308 **a) User Manual or Instructions for Use (IFU)**

309 Clear and detailed user manuals that outline the proper and secure operation of the medical device. This
310 should include instructions on how to set up and configure security features, possible cybersecurity hazards
311 that the device may pose, as well as best practices for maintaining the security of the device.
312

313 **b) Security Guidelines**

314 Specific security guidelines and best practices that users should follow to ensure the security of the device
315 and any associated data.
316

317 **c) Troubleshooting and Support**

318 Information on how to troubleshoot security-related issues and where to seek support if security concerns or
319 incidents arise.
320

321 **d) Software and Firmware Updates**

322 Guidance on how to apply software and firmware updates to the device to address security vulnerabilities and
323 ensure that the device is running the latest secure versions.
324

325 **e) Contact Information**

326 Clear contact information for the manufacturer's support team or security response team, so users can easily
327 report security issues or seek assistance.
328

329 **f) Security Certifications and Compliance**

330 Documentation of any security certifications or compliance standards that the device meets, providing users
331 with assurance of its security measures.
332

333 Customer Security Documentation

334 When it comes to Customer Security Documentation for medical devices, it's essential to provide comprehensive
335 and user-friendly information to guide users on how to operate the device securely. Manufacturers should also
336 effectively communicate relevant security information when operating the medical device in its intended
337 environment. The following elements should be considered:
338

- 339 • Provide users with detailed instructions on the necessary supporting infrastructure requirements to ensure
340 the device operates as intended.
- 341 • A detailed explanation of how the device is or can be fortified through secure configurations. These secure
342 configurations may involve endpoint protections such as: anti-malware, firewalls/firewall rules, whitelisting,
343 security event parameters, logging parameters, and physical security detection.
- 344 • Provide technical instructions, when necessary, for secure network deployment and servicing, along with
345 guidelines for users on how to respond when a cybersecurity vulnerability or incident is detected.
- 346 • An explanation of how the device or supporting systems will alert the user when anomalous conditions
347 are detected, if feasible. Types of security events may include configuration changes, network anomalies,
348 login attempts, and anomalous traffic.
- 349 • An explanation of the methods for retaining and recovering device configuration by an authenticated
350 privileged user.
- 351 • An outline of the security risks and consequences associated with changes to the security configuration
352 or the usage environment.
- 353 • A description of the systematic procedures for authorized users to download and install updates from the
354 manufacturer.
- 355 • Information regarding the End of Support (EOS) for device cybersecurity.
- 356 • A Software Bill of Materials (SBOM).
357

358 Due to the potentially sensitive nature of these information, which may disclose the strengths and weaknesses of
359 a medical device's cybersecurity; it is advisable for the manufacturers to establish a secure communication channel
360 for distributing such information to the users.
361

362 **6.5 Post-Market Plan**

363 **Post-Market Plan** - Developing a plan for on-going post-market activities, including monitoring, timely detecting,
 364 and addressing any security issues or emerging threats that may arise after the device has entered the market.
 365

366 Key considerations for the post-market plan include:

- 367 1. Post-market Vigilance
 368 2. Vulnerability Disclosure
 369 3. Patching and Updates
 370 4. Recovery
 371 5. Information sharing



372 Figure 3: Key considerations for the post-market plan.
 373
 374

375 By addressing these pre-market elements, manufacturers can enhance the cybersecurity of their medical devices
 376 and contribute to the overall safety and reliability of the healthcare technology and services provided.
 377

378 **6.6 Software Bill of Materials (SBOM)**

379 The concept of SBOM was initiated by US National Telecommunications and Information Administration (NTIA) in
 380 2018 to address software transparency. NTIA defined SBOM as a “list of one or more identified components, their
 381 relationships, and other associated information.”
 382

383 In short, SBOM is a comprehensive list of the software components used in building a particular application or
 384 system. This includes all the open-source and third-party components, libraries, and dependencies that are utilized
 385 in the development of the software.
 386

387 The adoption of SBOM has become increasingly important, especially in the context of cybersecurity. Leveraging
 388 on SBOM allows organizations to track and manage the software components used in their systems, which is
 389 essential for identifying and addressing potential vulnerabilities, the “weak link” and security risks in the software
 390 supply chain.
 391

392 In the context of medical devices, having an SBOM is particularly important as it enables manufacturers, users and
 393 healthcare providers to understand the software components and potential security implications. It also facilitates
 394 the tracking of software updates and patches, aiding in the maintenance of a secure and reliable medical device
 395 ecosystem.
 396

397 While the selection of SBOM formats is out of the scope of this guide, medical device manufacturers should adhere
 398 to recognized SBOM formats to ensure interoperability and facilitate data exchange. When generating an SBOM,
 399 choosing a machine-readable format is vital for automated processing and analysis. The following are the SBOM
 400 elements to be considered:

- 401
- 402 • Author name - denotes the entity (such as an individual, organization, or similar) responsible for producing
 403 the SBOM file.
 - 404 • Timestamp - a record of the date and time when the SBOM data was assembled.

- 405 • Software component vendor (supplier) - the entity responsible for creating, defining, and identifying
406 components. The software component vendor name should typically refer to the legal business name
407 used for commercial software.
- 408 • Software component name - the designation given to a software unit by the original supplier.
- 409 • Software component version - the identifier assigned by the supplier to denote a change in the software
410 from a previously version.
- 411 • Unique Identifier – identifiers used to recognize a component or function as a look-up key for relevant
412 databases.
- 413 • Relationship - explains how an upstream component X is incorporated into software Y.
414

415 The following use cases demonstrate on how SBOMs play a crucial role in enabling organizations to respond to
416 cybersecurity incidents, assess risks, communicate with vendors, plan remediation efforts, and maintain
417 compliance within the complex and rapidly evolving healthcare technology ecosystems.
418

419 **6.6.1 Use Case #1: Medical Device Manufacturer's Security Compliance**

420 **Scenario:**

421 ABC Medical Devices Ptd Ltd is a manufacturer of advanced medical imaging equipment. They are committed to
422 ensuring the security and integrity of their devices to protect patient data and maintain the reliability of their products.
423

424 **Use of SBOM:**

425 ABC Medical Devices utilizes SBOM as part of their cybersecurity and risk management strategy. When developing
426 their medical imaging equipment, they maintain a comprehensive SBOM that lists all the software components,
427 libraries, and dependencies used in building the device's software.
428

429 Transparency and Compliance:

430 The SBOM allows ABC Medical Devices to maintain transparency and compliance with regulatory requirements
431 related to software components and security standards. It provides a clear overview of all the software elements
432 used in their medical devices, including open-source and third-party components.
433

434 Vulnerability Management:

435 By maintaining an up-to-date SBOM, ABC Medical Devices can proactively monitor and manage potential
436 vulnerabilities associated with the software components used in their devices. They can stay informed about
437 security advisories, patches, and updates for the components listed in the SBOM, and thus update the users
438 promptly with the information.
439

440 Supply Chain Security:

441 The SBOM enables ABC Medical Devices to assess the security posture of their software supply chain. They can
442 evaluate the security practices of their software vendors and ensure that the components used in their devices
443 meet the necessary security standards.
444

445 Incident Response and Remediation:

446 In the event of a security incident or vulnerability disclosure related to a software component, the SBOM allows
447 ABC Medical Devices to quickly identify the affected devices and take appropriate remediation actions, such as
448 applying patches or updates to mitigate the risk.
449

450 Overall, the use of SBOM empowers ABC Medical Devices to maintain a secure and compliant software supply
451 chain, proactively manage vulnerabilities, and respond effectively to security incidents, thereby enhancing the
452 cybersecurity of their medical imaging equipment.
453

454 **6.6.2 Use Case #2: Cybersecurity Incident Response and Remediation**

455 **Scenario:**

456 XYZ Healthcare is a large hospital network that relies on a variety of medical devices and software systems to
457 deliver patient care. They prioritise cybersecurity to protect patient data and ensure the reliability of their healthcare
458 technology infrastructure.
459

460 **Use of SBOM:**

461 XYZ Healthcare leverages SBOM as a critical component of their cybersecurity incident response and remediation
462 strategy. They require SBOMs from their medical device manufacturers, IT and software vendors to ensure
463 transparency and visibility into the software components used in the devices and systems deployed across their
464 network. This information is also part of the requirements in the procurement process of XYZ Healthcare.
465

466 Incident Response:

467 In the event of a cybersecurity incident or the discovery of a software vulnerability, XYZ Healthcare utilizes the
468 SBOMs provided by their vendors to quickly identify the affected software components and devices within their
469 network.

Note: This copy is a draft, for consultation only.

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Risk Assessment:

The SBOMs enable XYZ Healthcare to conduct rapid risk assessments by understanding the software supply chain dependencies and identifying potential security implications associated with the affected components.

Vendor Communication:

Armed with SBOMs, XYZ Healthcare can effectively communicate with their device manufacturers, IT and software vendors to request relevant security patches, updates, or mitigation strategies to address the identified vulnerabilities.

Remediation Planning:

The SBOMs serve as a foundation for developing targeted remediation plans, allowing XYZ Healthcare to prioritise and apply security updates to the affected devices and software components in a timely manner. XYZ Healthcare should liaise the manufacturer to ensure the implementation of appropriate interim and final measures.

Compliance and Reporting:

SBOMs support the compliance efforts by providing a clear record of the software components and their associated security status, which is essential for regulatory reporting and demonstrating due diligence in managing cybersecurity incidents.

By leveraging SBOMs in their incident response and remediation processes, XYZ Healthcare can effectively manage and mitigate cybersecurity risks, ensuring the security and integrity of their healthcare technology infrastructure.

6.7 Additional consideration - Devices with Artificial Intelligence (AI)

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AI is rapidly emerging as a key field in today's world, with its integration into medical devices enhancing workflow, aiding in diagnosis, and predicting risk of diseases. While AI holds the potential to increase work efficiency and reduce costs, it also may pose intentional and unintentional harm. The swift advancement and uptake of AI could make it a prime target for malicious cyber actors. If a medical device is compromised, it can lead to incorrect diagnoses, treatment errors or even life-threatening situations for patients. With the introduction of Generative AI, new threats such as: prompt injections, hallucinations, spreading of misinformation and unintentional data leaks could emerge. Consequently, these new threats that must be addressed alongside with standard cyber threats.

To ensure the deployment of a robust and secure AI system, the following key areas to be considered throughout the AI system development cycle: security in AI model design, security during AI development (including AI supply chain security), security of AI during deployment, and the security of AI during operation and maintenance post-deployment. Device manufacturers and healthcare providers should consider implementing robust data privacy measures, regularly monitor AI outputs for accuracy and ensure transparency in AI-generated content. Additionally, continuous security assessments and updates to cybersecurity protocols are essential to stay ahead of emerging threats.

In addition, AI developers should be responsibly releasing the AI system after subjecting it to thorough security evaluation. All known limitations of the AI system should be clearly communicated to the users. Users should evaluate the pros and cons of the AI system and its' limitations before deploying it for actual use.

515 **7 Post-market stages**

516 This section described the three post-market stages in the TPLC of the medical device, namely the **Support stage**,
 517 **Limited Support stage** and **End of Support stage**. At each post-market stage, there is different degree of
 518 involvement by the medical device manufacturers and users (including the healthcare providers) in terms of the
 519 responsibility and the support given for the device. As the device reaches its End-Of-Life (EOL) and End-Of-Support
 520 (EOS), there is a transfer of responsibility from the manufacturer to the user.
 521

522 **7.1 Support stage**

523 At the post-market Support stage, manufacturers should provide comprehensive cybersecurity support to
 524 healthcare providers for the devices in use or deployed (e.g. software patches, software and hardware updates,
 525 etc.). Users should have access to the information for them to perform their assessment on the cybersecurity of
 526 the device.
 527

528 **7.1.1 Procurement and installation**

529 During the procurement and installation phase, manufacturers should provide the following support:
 530

- 531 • Provide **Product Security Documentation** [e.g. Software Bill of Material (SBOM), security test reports]: This
 532 security documentation helps to provide product security information to the user to aid them in the risk
 533 management during the procurement and deployment of the medical devices.
 534
- 535 • Provide **Product Life Cycle Documentation** [e.g. key milestones including the cybersecurity EOL and EOS
 536 dates (if available)]: This life cycle documentation provides the user the necessary information to manage the
 537 security of the device over the course of the device lifecycle.
 538
 - 539 ○ Information to be provided by manufacturers / requested by healthcare providers includes:
 - 540 ▪ The device's operating system
 - 541 ▪ The version deployed, including the known open software anomalies in each version
 - 542 ▪ Identification of software components
 - 543 ▪ Ports and services necessary for the device to function appropriately
 - 544 ▪ Firewall rules that can be leveraged to isolate the device and maintain function
 - 545 ▪ Expected date of service changes
 - 546 ▪ The extent of any available maintenance after the changes
 - 547 ▪ Anti-malware capabilities and appropriate definitions (what can be scanned)
 - 548 ▪ Security scanning capabilities and appropriate scanning definitions (how to scan)
 - 549 ▪ Security logging capabilities
 - 550 ▪ Device backup and restore procedures
 - 551 ▪ Notification method to receive vulnerability notification
 - 552 ▪ Administrative accounts and the ability to manage through a privilege access management
 553 tool
 - 554 ▪ Additional compensating controls (Note: Compensating controls refer to a type of risk control
 555 measure that is deployed in lieu of, or in the absence of, risk control measures implemented
 556 as part of the device's design.)
 - 557 ○ The schedule of service changes and the extent of any available maintenance (applicable for the
 558 third-party component as well) should be clearly communicated.
- 559 • **Contractual agreement** between the manufacturers and healthcare providers for the commitment on the
 560 period of cybersecurity support to be provided.
 561

562 **7.1.2 When device is in use**

563 While the device is in use, it is important that the communication between manufacturers and healthcare providers
 564 are well-maintained. This is to allow for prompt and adequate support in situations when vulnerabilities emerge.
 565 Both the manufacturers and healthcare providers should take note of the following:
 566

- 567 • Manufacturers should provide **updated Product Security and Product Life Cycle Documentation**. There
 568 will be changes to the device throughout its life cycle. As such, it is crucial for manufacturers to update the
 569 healthcare providers of the changes so that they are aware of the new risks involved.
 570
- 571 • Manufacturers should provide the relevant **Vulnerability and Patching Information**. If there is any
 572 vulnerability discovered, manufacturers should keep healthcare providers informed and provide any
 573 mitigations that are available. Such communication between the manufacturer and healthcare providers can
 574 help to prevent patient harm or device/service disruption.
 575
- 576 • **Monitoring of software components** (e.g. operating systems, third-party components) are necessary to
 577 maintain performance of the device, ensure adequate support and allow smooth transition to new components
 578
 579

Note: This copy is a draft, for consultation only.

(e.g. due to EOL/EOS of the component, or as a mitigation to reduce the risk of vulnerability, etc.). Such monitoring should be performed by both manufacturers and healthcare providers, e.g. using SBOM, and carry out risk assessment to determine the impact on the cybersecurity of the device. In such situations, the manufacturer informs the healthcare providers when any component reaches its EOL/EOS, or the healthcare providers engages the manufacturer in their planning for any component nearing EOL/EOS.

- It would be beneficial to include and consider the following information to allow for efficient monitoring:
 - Expected EOL/EOS date (if any)
 - SBOM
 - Any software upgrade option
 - Software changes schedule
 - Maintenance schedule
 - Risk analysis documentation (e.g. the available mitigation, any potential new risk, etc.)
- The support from manufacturers may reduce for component(s) until the device's EOS. However, manufacturer should still monitor and inform healthcare providers if there is any change to the risk profile of the device.
- **Post-market surveillance** of the device is necessary after device deployment. The activities include
 - a) Continuous monitoring of the device for potential security threats and anomalies. This involves the collection, documentation and review of all complaints received internally (e.g. during verification and validation) or externally (e.g. customer complaints).
 - b) Reporting of any adverse events and/or field safety corrective actions to regulatory authority.
 - c) Active engagement in risk management of the device. This allows for prompt management of resources, actions, etc. needed to address the identified security issues / risks impacting the device on an ongoing basis.
- **Cybersecurity training** should be provided for healthcare providers to raise awareness about potential threats and best practices. This is to ensure the healthcare providers understand the importance of security measures and to report if they identify any security concern, to allow for the safe and secure usage of the medical device.
- Manufacturers and healthcare providers are recommended to have a **Vulnerability Management system (VMS)** in place to review and assess vulnerabilities (both new and current) to ensure that the impact of the vulnerabilities to the medical device is reduced to the minimum and with proper security measures (e.g. software updates or patches) implemented.

The principles to establish an effective VMS include:

- a) **Apply update by default:**
By applying update by default, it prevents situations where some updates (feature update or security update) are missed and thus make the medical device 'open' to the vulnerabilities.
- b) **Identify assets:**
It is helpful to have a list of components used in the medical device with all the relevant information indicated (e.g. the version, the supplier, EOL/EOS dates, etc.). It is similar to SBOM (refer to the section above).
- c) **Triage and prioritise update:**
Sometimes, it is necessary to tackle some vulnerabilities over the others. Therefore, it is important to triage and prioritise some updates to be implemented first to reduce the critical risks.
- d) **Justification for not implementing an update:**
Management of cybersecurity risks is part of the device's overall risk management structure. If an update is deemed not required, the rationale for not having an update and the risk assessment of the issue should be documented and assessed by all the relevant parties (e.g. senior management).
- e) **Verify and regularly review the system:**
Regular review of the system will allow the system to be up-to-date to identify and review any new threats or vulnerabilities, as well as to monitor the current vulnerabilities. This will ensure the security measures are also updated for the medical device.

7.1.3 Transfer of responsibility

The transition from Support stage to Limited Support stage will result in the transfer of responsibility between the manufacturers and healthcare providers. It is shared responsibility from both sides where manufacturers are capable to provide the maximum support for the device at the start of TPLC, but decreasing support as the device moves towards EOL and EOS of the device. As the device gets nearer to its EOL and EOS, healthcare providers has increasing responsibility to ensure the safety and efficacy of the device.

647 The best time to start the transition process is approximately 2 to 3 years before the EOS. Manufacturers should
 648 inform the healthcare providers the expected EOS date, to allow sufficient time for the healthcare providers to
 649 evaluate, plan and budget for the retirement and/or replacement of the device. During this transition process, both
 650 manufacturers and healthcare providers should work closely together to allow a smooth transition.

651
 652 Close communication between the manufacturers and healthcare providers will allow each side to understand their
 653 own responsibilities as well as the risks for the device. The following listed some considerations that manufacturers
 654 and healthcare providers should consider during this transition process:

655
 656 Table 1: Consideration by manufacturer and healthcare providers during the transition from Support stage to
 657 Limited Support stage.

For manufacturers	For healthcare providers
<ul style="list-style-type: none"> • Provide updated Product Security Documentation. • Provide information on the configurable security options that may be implemented at EOL/EOS. <ul style="list-style-type: none"> ○ Software only ○ Partial software and hardware only ○ Complete replacement: <ul style="list-style-type: none"> (i) Replacement options and strategy (ii) Available device models and functionality • Inform user on the configurable security options. 	<ul style="list-style-type: none"> • Assess own ability to manage the device from a cybersecurity and clinical use perspective. • Identify possible support from third-party and additional resources required which may help to manage and support the device. • Assess any potential device replacement opportunities.

658

659 **7.2 Limited Support stage (Between EOL and EOS)**

660 The Limited Support stage is a crucial stage for medical device as it reached the EOL and moving towards the
 661 EOS of its life cycle. Both manufacturers and healthcare providers should continue with the close communication
 662 from the Support stage. Information related to the product, possible risks, mitigation and device replacement
 663 options should be made available.

664
 665 At this stage, the manufacturers should inform the healthcare providers of the reduction of support to Limited
 666 support. It includes the timeline until EOS, the alerts when some parts of the medical device are no longer supported,
 667 any available software updates, any recommended compensating controls. Implementation of compensating
 668 controls (i.e. alternative risk control measures) at this stage will be necessary as the device with limited support will
 669 not have sufficient protective measures (e.g. no more software updates) against the vulnerabilities.

670
 671 With lesser support from the manufacturer, the healthcare providers would need to consider if they can continue to
 672 use the medical device or to purchase a new device.

673
 674 The healthcare providers should consider the following points before they decide to continue using a medical device
 675 near EOS.

- 676 • The risk of using the medical device when the security could be impacted with limited support from
 677 manufacturers.
- 678 • The usability of the medical device, e.g. whether the limited features still remain applicable to the patients, in
 679 cases where there are no software updates (in terms of functionality or security).
- 680 • The resources to support the medical device, e.g. compensating controls, maintenance costs.
- 681 • The impact to the patients if the medical device cannot be used and an alternative is required.

682
 683 It is possible that the healthcare providers will purchase a new device after all the above considerations. However,
 684 the healthcare providers should also think about the potential gap from the EOS of the current device till the
 685 availability of the new device. It is therefore recommended to begin this process approximately 2 to 3 years before
 686 the EOS (refer to the Transfer of responsibility above).

687

688 **7.3 End of Support stage (EOS onwards)**

689 At this EOS stage, full responsibilities are transferred to the healthcare providers where they need to manage the
 690 device cybersecurity risks without assistance from the manufacturers. The first step for the healthcare providers is
 691 always to assess if they have the capability to handle this transferred responsibility. If necessary, the manufacturers
 692 may consider a gradual transfer of responsibility to the healthcare providers, to allow the healthcare providers to
 693 have sufficient preparation to take over the responsibility.

694
 695 Similar to the previous stages in post-market phase, the manufacturer should provide all the necessary product
 696 security information to healthcare providers and to inform the public on the move of the medical device to EOS
 697 stage. This is critical as it will allow the healthcare providers to perform their assessment / management on the

698 cybersecurity risks associated with the medical device, or for the public to understand the potential risks in
699 continuing the usage of such EOS device. Besides the cybersecurity risks involved, the potential patient risks
700 should be communicated as part of post-market expectations via reactive vulnerability management.
701

702 For the healthcare providers, the same considerations in Limited Support stage remain applicable. In the case
703 where the healthcare providers continue to use the medical device past its EOS date, the following is recommended
704 to allow healthcare providers to have proper management over the cybersecurity risks of the medical device.
705

- 706 • Implement strong cybersecurity program (e.g. resources to manage the increasing risk).
- 707 • Implement robust inventory management system (including vulnerability database for third-party components).
- 708 • Enhance risk measures (e.g. compensating controls such as limiting physical access, removing remote access,
709 firewall, network segregation/isolation).
- 710 • Periodically evaluate the availability of alternative medical device and re-assess the decision to use the current
711 device past its EOS.

712
713 With proper risk management measures in place, it will help to ensure the security of the medical device after EOS.
714 In addition to the above measures, it is also recommended that the healthcare providers
715 are trained and be informed on the usage of the medical device in a safe and secure manner and on how to spot
716 and identify any unusual device behaviour. This is to mitigate any risk during the usage of the device.
717

718 **7.4 Summary**

719 The post-market stage of medical device cybersecurity encompasses the entire period after a device has been
720 released to market. It can be divided into three main phases:

- 721 1. Support Stage: This is the primary phase of the device's operational life. During this stage, the manufacturer
722 provides active maintenance and regular updates. Key activities include:
 - 723 • Continuous monitoring for new vulnerabilities
 - 724 • Releasing timely security patches and updates
 - 725 • Providing technical support to users
 - 726 • Conducting ongoing risk assessments
 - 727 • Implementing cybersecurity improvements as needed
- 728 2. Limited Support Stage: As the device ages, it may enter a phase of limited support. During this time:
 - 729 • The frequency of updates may decrease
 - 730 • Support may be more focused on critical security issues
 - 731 • The manufacturer may encourage migration to newer, more secure versions
 - 732 • Legacy systems may require additional security measures
- 733 3. End of Support Stage: This final stage occurs when the manufacturer no longer provides active support for the
734 device. Key considerations include:
 - 735 • Clear communication to users about the end of support
 - 736 • Guidance on securely decommissioning devices
 - 737 • Strategies for managing cybersecurity risks in legacy devices that must remain in use
 - 738 • Potential need for compensating controls to protect unsupported devices

739 Throughout all these stages, effective cybersecurity management requires collaboration between manufacturers,
740 healthcare providers, and cybersecurity experts. The goal is to maintain the security and integrity of medical devices
741 throughout their entire lifecycle, even as support levels change over time.
742

743 The following figure provides the overview of the cybersecurity best practices in the TPLC of the medical device.
744
745
746
747

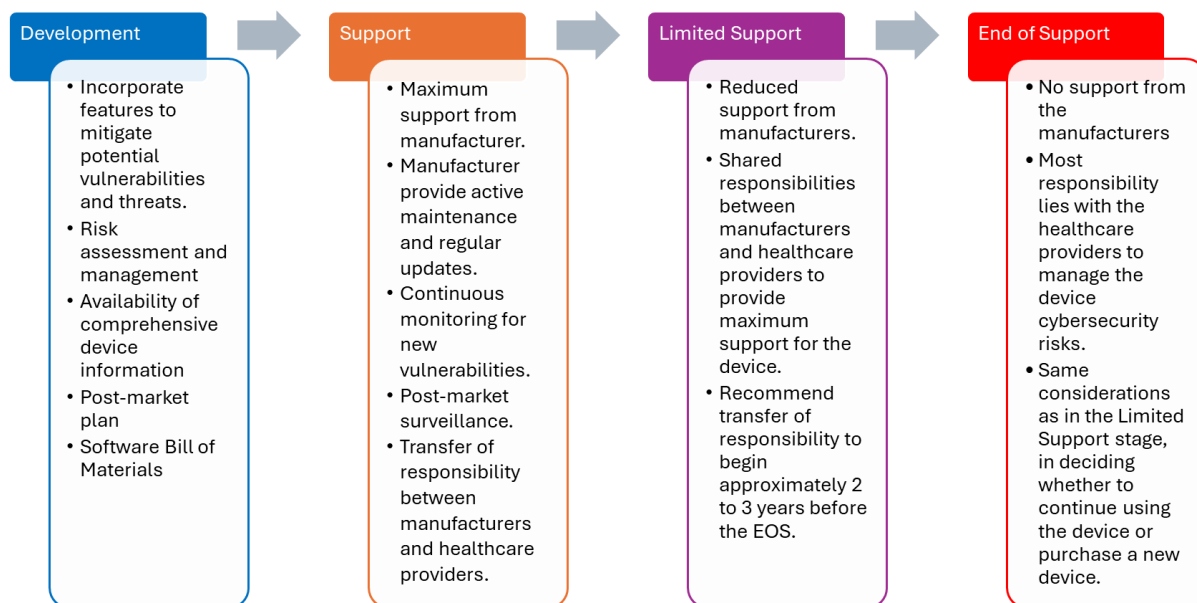


Figure 4: Overview of the cybersecurity best practices in the TPLC of the medical device

748
749
750

751 **8 Conclusion**

752 The landscape of medical device cybersecurity is dynamic and complex, requiring constant vigilance and
753 adaptation from the manufacturers and healthcare providers involved. This document has outlined comprehensive
754 cybersecurity best practices for medical devices, spanning both pre-market and post-market stages of the device's
755 TPLC.

756
757 In the pre-market stage, we have emphasised the critical importance of integrating security features from the outset
758 of device development. By incorporating robust risk management strategies, thorough security testing, and
759 transparent documentation including SBOM, manufacturers can lay a strong foundation for device security. These
760 premarket considerations are not merely regulatory checkboxes, but essential steps in creating resilient, secure
761 medical devices that can withstand evolving cyber threats.

762
763 The post-market stage, with its support, limited support, and end of support phases, underscores the ongoing
764 nature of cybersecurity in medical devices. As threats evolve and new vulnerabilities emerge, the need for
765 continuous monitoring, timely updates, and proactive risk management becomes paramount. Even as devices
766 approach the end of their supported lifecycle, cybersecurity remains a critical consideration, requiring careful
767 planning and mitigation strategies.

768
769 In conclusion, cybersecurity in medical devices requires shared responsibility and close communication between
770 the manufacturers and healthcare providers. By embracing these best practices and fostering a culture of security,
771 we can build a safer, more resilient healthcare ecosystem that leverages the full potential of medical technology
772 while protecting the privacy and safety of patients.

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