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Medical Device Lifetime

Addressing the lifetime requirements of the MDR (EU) 2017/745

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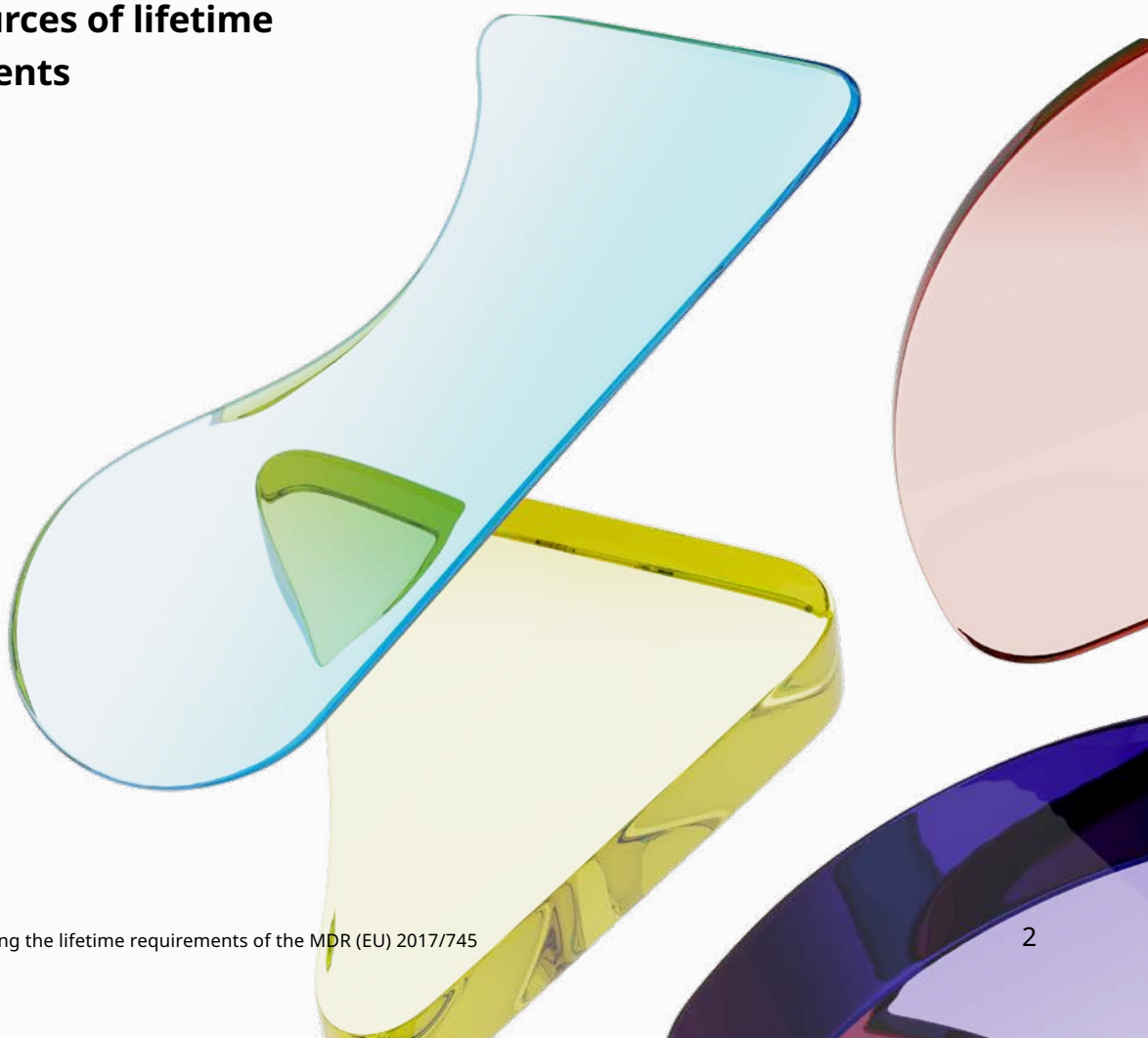


Introduction

The Medical Device Regulation (MDR) (EU) 2017/745, Annex I, General Safety and Performance Requirements, GSPR 6, states:

> The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

To demonstrate compliance with GSPR 6, a manufacturer must determine the lifetime of their device and assess the effects of the device's lifetime on safety and performance.

The manufacturer must also consider the device's lifetime when developing marketing strategies, maintenance regimens, and post-market surveillance plans through the device lifecycle. Furthermore, when lifetime affects safety and performance, the manufacturer must inform the user of the steps to take when performance changes and how to manage the device's end-of-life, including any warnings or precautions to facilitate safe disposal (GSPR 23).

This paper provides a practical, informative guidance to assist manufacturers in specifying the lifetime of a medical device based on its design characteristics to meet the regulatory requirements of the MDR.

Definition of lifetime

Basic principles

The MDR does not define medical device lifetime in a specific manner, and there is no consistent definition used in standards or guidance documents, which may lead to uncertainty for devices with a shelf life and those devices that are reusable. However, the definition of the device's lifetime and shelf life ensures that users and patients are informed of the device's achievable safety and performance. The user and patient need to know how long the device will last for safe use, considering its intended purpose, including from the point of first use. So, there is a need for clear communication between the manufacturer, users, and patients for the identification of the device's lifetime from the point of first use until disposal or decommissioning, considering any activities needed for maintenance during that time.

Similarly, the MDR does not define shelf life. Typically, shelf life is defined as how long a device can be stored before use following manufacture. Shelf life is essential for sterile devices with an expiration date. However, manufacturers must consider the effects of storage on their devices, whether sterile or not and how this may impact safety and performance.

The manufacturer should not combine the shelf life and lifetime measurement to create an overall lifetime value because lifetime can be specified in several ways; for example, usage cycles per procedure, or cleaning and sterilization cycles. As a result, the combination of shelf life and lifetime may be impractical in some cases and therefore it is more straightforward to state shelf life and lifetime as separate variables. However, when verifying lifetime, the manufacturer should consider the impact of the shelf life on the lifetime, notably if the device, or its components and materials may degrade over time, and as to whether the lifetime claims would be met by devices stored for the maximum shelf life in worst case conditions. The manufacturer should consider if any maintenance or replacement of the device or its components is needed to

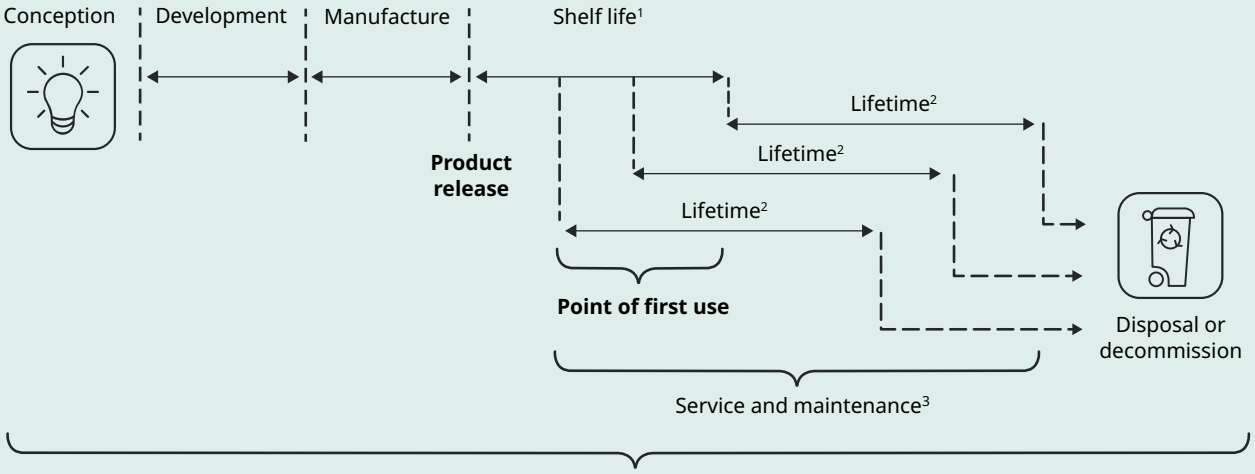
maintain shelf life. Batteries, for example, may lose their charge over time or could be affected by the conditions of storage, and this, therefore, affects the lifetime of the component and the device.

Lifetime should not be confused with the device's design and development and phased life cycle of ISO 14971. The life cycle model shown below encompasses the device's conception, development, manufacture, service, and maintenance, disposal, or decommissioning. The model allows the manufacturer to support business management and the complete time frame of all activities associated with design, manufacture, and post-market phases. However, the manufacturer can influence and determine the device's lifetime at each product lifecycle stage.

Figure 1 provides a simple representation of the principles discussed above.

Figure 1 delineates the shelf life, lifetime, and lifecycle, showing lifetime as the point of first use until disposal or decommissioning. However, the lifetime in this depiction could commence anywhere within the shelf-life period for devices with a defined shelf life. The manufacturer may extend the shelf life and lifetime through planned

Figure 1: Medical device life cycle encompassing shelf life and lifetime



ISO 14971: All phases in the life of a medical device, from initial conception to final decommissioning and disposal

[1] Time from date of manufacture to the claimed use-by date. Not all devices have a use-by date. However, the storage conditions and time should be considered.

[2] Number and/or the period of subsequent uses

[3] Service and maintenance can be used to extend lifetime

preventative maintenance activities, for example, the charging of batteries prior to loss of charge or replacing components that are known to wear over time prior to failure or have a short shelf life to avoid the shelf life being exceeded.

Units of measurement

Typically, lifetime is measured in units of time, minutes, hours, days, months, or years. However, the manufacturer may use other quantitative/ numerical units depending on the device characteristics, including, for example, usage cycles, sterilization cycles, radioactive decay, or other appropriate, limited measures. The lifetime, as far as possible, should be achievable without reliance on user interaction, which may introduce additional risks or hazardous situations including use errors or misuse.

The manufacturer may also need to consider the device's therapeutic and implantation lifetime. For example, implantable or administered substances or radioactive sources with a short half-life will have a period of therapeutic benefit (functional lifetime) and then remain in the patient until their

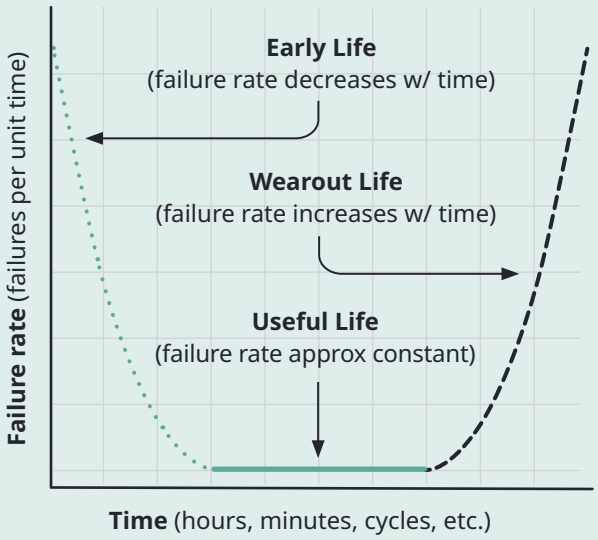
planned removal or until the patient dies, years or decades later (the biological lifetime). Similarly, for example, the manufacturer of bone screws will design them to meet specific load conditions while the bone heals (functional lifetime). However, they will remain in place until the patient's death, years or decades later (the biological lifetime).

Lifetime and device reliability

The reliability and functional safety characteristics of the components used within a device will determine its lifetime. Reliability is a system's ability to function under stated conditions for a specified duration. However, reliability may not be the only limiting factor; the patient's physiological response to the device may also limit its useful lifetime. For example, the lifetime of an implantable glucose sensor may be limited by the time it takes the patient's body to encapsulate[1] it.

Typically, the reliability of a device can be represented by a bathtub curve, Figure 2, which is a combination of early life failures when the device is first used, useful life failures with a constant failure rate, and finally, the rate of wear-out failures as the device exceeds its design lifetime.

Figure 2: Bathtub curve



Design and pre-production controls such as HALT (highly accelerated life testing) and production controls such as burn-in and Highly Accelerated Stress Screening (HASS) can detect weaknesses and protect against or manage early life failures from changes in components, processes, or suppliers.

Service and maintenance regimens can reduce early life and useful life failures and potential for post market incidents when appropriately used considering the components of the device and device use, periodicity and to device safety and performance through lifetime until decommissioning or disposal.

Appropriate lifecycle management, maintenance and end-of-life programs can mitigate the risks associated with wear-out failures. Similarly, upgrade programs may allow users to transition to new devices, versions, or variants. This may be a particularly useful tool where the device is (or includes) software.

Failures identified through analysis may indicate that the device is not meeting the defined lifetime, service life or device safety and performance. The manufacturer should address

the root causes of all failures to improve product reliability, safety, and effectiveness through appropriate processes. For example, design, software development, manufacture, risk management, usability, post market processes and potential impact to device decommissioning and disposal.

[1] The body automatically reacts to any foreign body it detects within it and attempts to isolate it by creating a barrier of scar tissue, in some cases affecting the performance of the device.

Characteristics affecting lifetime

The device's technical characteristics and other parameters affecting safety and performance of intended use vary between medical device types. The manufacturer must fully understand the characteristics that will determine the device's lifetime, including the clinical and biological environment in which the device operates.

Table 1 provides examples of several devices and considers some technical and clinical characteristics that may determine the device's lifetime.

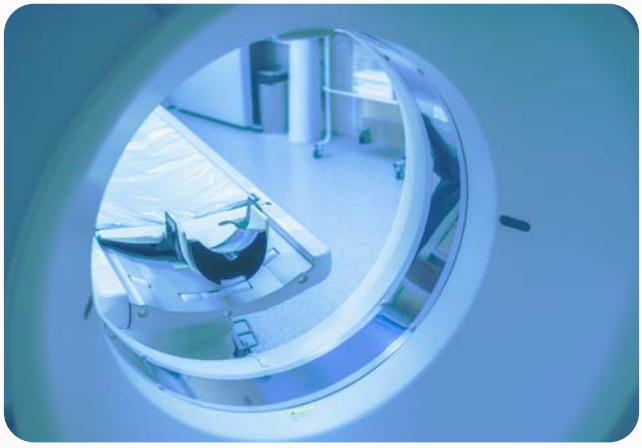


Table 1: Device lifetime technical and clinical considerations

Device	Technical	Clinical and biological
The administration set for a peristaltic infusion pump	The peristaltic action on the pumping segment of the administration set degrades the silicone, releasing particulates into the infusate. Furthermore, physical wear may lead to leakage.	Thrombus formation leads to occlusion, particularly at low infusion rates. The risk of infection increases with time. Therefore, the user must regularly change the administration set.
A mechanical replacement heart valve	ISO 5840-1[2] requires the valve to be able to operate for 400 million cycles, equating to approximately ten years of use.	The ability to prevent thrombus formation may limit the valve's lifetime. The patient must take anticoagulants for the valve to achieve its technical lifetime.
Orthopaedic bone screws	The screws must withstand the load they will be subject to before bone healing.	The risks associated with removing the screw may be high. Therefore, the screws may remain in place for the patient's lifetime.
Magnetic Resonance Imaging (MRI) scanner	The component wear maintenance regime, critical component ratings, high integrity components, specification for intended use, and parts availability for planned maintenance will limit the MRI scanner's lifetime.	Advances in state-of-the-art[3] may result in newer systems having improved functionality, image quality, and diagnostic capabilities, forcing older systems into obsolescence.

[2] ISO 5840-1, Second edition 2021-01, Clause 7.2.5.3 Device structural component fatigue assessment

[3] ISO 14971:2019 defines state of the art as the developed stage of technical capability at a given time as regards products, processes (3.14) and services, based on the relevant consolidated findings of science, technology and experience Note 1 to entry: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the "generally acknowledged state of the art."

Device	Technical	Clinical and biological
Syringe driver for infusing drugs and other fluids	The moving components and those subject to mechanical forces will wear. The rechargeable battery will have a lifetime based on the number of charge/discharge cycles or time. Long storage periods without use, or constantly being on charge may also reduce the batteries lifetime. Mechanical springs or buttons may have been rated for force, pressure, and number of activations. Ratings for critical components and functional design (for example, material types used) may also affect device lifetime and reliability for the intended use. The maintenance regime and the availability of components and parts will limit the syringe pump's lifetime.	The syringe pump does not interact with biological tissues. However, several clinical uses or activations or clinical use errors, such as spillage, may limit its lifetime. Delay or failure to conduct maintenance and service activities may also limit the devices lifetime.
Cardiac pacemaker	The battery capacity and the power consumption of the various operating modes will determine the lifetime. ISO 14708-1[4] requires the pacemaker to have an elective replacement indicator that warns about energy source depletion. Advances in state-of-the-art may result in newer systems having improved battery life and pacing functionality, forcing older systems into obsolescence.	Vascular fibrosis and lead encapsulation affect the functioning of the pacemaker. Higher lead impedance may result in a higher pacing voltage and reduced battery life.
Implantable glucose sensor	The reader's rechargeable battery will have a lifetime based on the number of charge/discharge cycles or time. The sensor will be subject to risks of patient activities and adhesive may become loose or ineffective.	The sensor becomes encapsulated over time, causing inaccurate glucose measurements. The sensor incorporates a Dexamethasone collar to increase the sensor's life by slowing down encapsulation. The device is in contact with bodily tissues and fluids, which may impact the device's functional safety and effectiveness.

[4] ISO 14708-1, Second edition 2014-08-15, Implants for surgery – Active Implantable Medical Devices – Part 1: General requirements for safety, marking and for information to be supplied by the manufacturer.

Device	Technical	Clinical and biological
Implantable radioactive seeds for the treatment of prostate cancer	The seeds are permanent implants. Therefore, the manufacturer must ensure the capsule containing the radioactive source remains hermetically sealed for the patient's lifetime.	The decay of the radioactive source determines the therapeutic lifetime. The radioactive energy will decay to a point where it no longer has a therapeutic effect.
Reusable endoscope for colonoscopy	The endoscope is subject to an abrasive cleaning regime followed by steam sterilization. The cleaning and sterilization regime will degrade the plastic coatings, becoming brittle and failing. The manufacturer should determine the lifetime by the number of cleaning and sterilization cycles before failure and by any component limitations or other wear characteristics related to the intended use.	With each use, the healthcare professional may incur or induce mechanical and functional wear to the device depending on the care and handling or usage time of the procedures and to degradation from sterilisation incurred.
Drug eluting stent	The stent is subject to mechanical forces, including bending, compression, and torsion, while stabilizing the blood vessel. BS EN ISO 25539-2[5] includes requirements for computational modelling and in-vitro fatigue testing, the results of which support the manufacturer's lifetime claims.	The drug element acts to inhibit localized cellular growth and reduce plaque build-up. The availability of the drug to have a therapeutic effect must be considered when determining lifetime. Clinical data will be required to substantiate claims for use and related to the drug.
Antimicrobial waterproof wound dressing	The ability of the dressing to seal, remain waterproof, and absorb exudate will contribute to its lifetime.	The antimicrobial action will be time limited and contribute to determining lifetime (i.e., the maximum wear time of an individual dressing).
Resorbable dental bone void filler	The bone void filler facilitates cellular growth and bone formation; therefore, the device's lifetime relies on clinical performance data.	The time it takes for the patient's tissue to regenerate and the bone void filler to be absorbed contributes to determining lifetime.
Bioprosthetic replacement heart valve using animal tissues	Like the mechanical heart valve, the manufacturer must ensure the mechanical integrity of the bioprosthetic heart valve over its claimed lifetime. Animal tissues are particularly susceptible to temperature, humidity, and microbial growth and must be stored appropriately to ensure that no tissue degradation affects their lifetime.	Calcification is a leading cause of bioprosthetic valve failure and contributes to determining lifetime.

[5] BS EN ISO 25539-2:2020 Cardiovascular implants. Endovascular devices-Vascular stents.

Device	Technical	Clinical and biological
Saline nasal spray (non-medicinal)	A saline nasal spray is used to treat dryness in the nasal passage, adding moisture and helping to dissolve dried mucous and clear particulates such as pollen. Bacterial contamination of the saline solution and bottle may contribute to determining the lifetime. The saline may have an expiry date related to its shelf life, but also an expiration period once opened.	Saline works by washing the nasal passage and is unlikely to have a therapeutic effect that determines its lifetime. However, some patients will tolerate its use better than others, and there will be an optimum time between doses.

The manufacturer should develop lifetime design input requirements based on the devices intended purpose and the user's safety and performance needs. Consideration should be given to individual component performance, compliance with standards, and usability within a risk management framework meeting the current acknowledged state-of-the-art.

The following aspects are examples that could influence the device's lifetime and should be considered by the manufacturer when specifying the device (the list is not exhaustive).

Environmental stresses

- Minimum and maximum operating temperatures
- Temperature cycling and thermal shocks
- Duration of operation
- Humidity
- Fluid ingress
- Microbial and particulate ingress
- Pressure
- Ionizing radiation
- Non-ionizing radiation (e.g., exposure to ultraviolet light, etc.)
- Static electric discharges
- Conditions of storage and transport
- Cycles of sterilisation

Electrical safety/Functional safety

- Component operating voltage, current, power, and temperature
- Electrical insulation breakdown
- Component aging
- Manufacturing faults (e.g., dry solder joints, poorly assembled crimp terminals, etc.)
- Fatigue of electrical connections due to mechanical stresses
- Redundancy and diversity of components used in the design and ability of the user to detect whether any failure(s) have occurred that may have affected the device safety and performance
- Replacement of component(s) and component availability
- Protective electrical measures (e.g., surge protection, EMI protection, etc.)
- Protection against incorrect connections

Mechanical stresses

- Shock and vibration
- Tension, torsion, shear, and compression
- Abrasion, adhesion, corrosion
- Low[6] and high[7] cycle fatigue
- Load and frictional deterioration

Stability

- Oxidization due to chemical reactions
- Self-discharge of batteries
- Shelf life of sterile and non-sterile products
- Battery performance characteristics
- Thermal degradation

User stresses

- Stresses experienced under standard use patterns and operating practices
- Home use where the operating environment is likely to be less controlled
- Use error(s) and foreseeable misuse as determined by risk assessment and usability engineering
- Unforeseeable misuse gathered as part of post-market surveillance (PMS)
- Device handling practices and local user guidelines

Manufacturing

- Manufacturing machinery and processes affecting the product quality and reliability, (e.g., component tolerances, curing of adhesives, pull force of crimps, fit and integrity of seals, etc.)
- Competency and training of the production staff to build products meeting the design requirements
- The quality of materials used in the device's construction
- Product testing during the manufacturing process

Maintenance and Refurbishment

Some devices can undergo maintenance to achieve their lifetime. While a manufacturer can maintain a device, it does not mean it has an infinite lifetime. Based on the wear characteristics of the replaceable components, manufacturers should understand which will limit the overall lifetime. For example, which component will need replacing first, how often components will need replacing and the availability of replacement parts.

MDR Article 2(31) defines 'fully refurbishing' a device. If a manufacturer successfully rebuilds a device already placed on the market or put into service or makes a new device from used devices. In that case, they must assign a new lifetime to the refurbished device to bring it into conformity with the Regulation. Use of refurbished parts to replace component parts will affect the lifetime of the device subject to refurbishment or repair and the manufacturer should consider the impact to the lifetime of the device following any such activities.

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[6] Low cycle fatigue is repeated plastic deformation (material is under load and stretches, changing shape e.g., bone screw under too much load).

[7] High cycle fatigue is repeated elastic deformation (material deforms and returns to original shape, e.g., a spring).

Reprocessing

MDR Article 17 allows for reprocessing single-use devices when permitted by national law. The legal person who reprocesses the device is considered the manufacturer and must assume the obligations in the Regulation, including those related to the reprocessed device's lifetime.

Software

The lifetime of standalone medical device software presents an interesting case. The software itself, being an algorithm, does not age. However, the manufacturer should consider the following:

- The software development plan, design, and configuration items, including software of unknown provenance (SOUP)
- Software changes due to improvements and the platform on which the software runs, (e.g., software version 1.0, may be replaced by 2.0, which has enhanced functionality)
- The software maintenance plan (i.e., how long does the manufacturer expect to support the software with bug fixes and updates?)
- The availability of the operating environment, including the hardware and operating system
- The need to maintain safety, security, and issue cyber security updates to address vulnerabilities
- How long is the software intended or designed to remain state-of-the-art?

The manufacturer should consider how the device will be maintained, including safety, security, interoperability, and changes in the state-of-the-art that may impact the intended purpose as part of defining lifetime in quantitative terms.

Lifetime and risk management

The manufacturer must consider the lifetime and probability of failures, for example, premature device failure, and where appropriate, their detectability during the risk assessment, and implementation of appropriate risk controls, functional safety, or other appropriate measures.

The following are valuable tools in identifying design, manufacturing, and limitations of clinical use that may affect lifetime:

- Design Failure Mode Effects Analysis (DFMEA)
- Production Failure Mode Effects Analysis (PFMEA)
- User Failure Mode Effects Analysis (uFMEA)
- Clinical risk assessment
- Processing or reprocessing risk assessments

The risk management standard, ISO 14971[8], is harmonized with the MDR and provides a risk management framework to assist with conformity for the relevant requirements.

Other standards and publications are also relevant for state-of-the-art, and further standards and common specifications may become harmonized with the MDR.

Documenting lifetime claims

The manufacturer must determine the expected lifetime of their device and declare it within the device's technical documentation. Furthermore, they must provide evidence to verify and support their claims. The Notified Body will audit the information for compliance with GSPR 6[9].

Where device malfunction could occur or performance changes can affect safety, (for example within or at the end of life) these could indicate that the device is not meeting the derived or declared lifetime. The manufacturer must evaluate root cause(s) and post market surveillance and the device history as applicable, provide the relevant evidence for mitigations, warnings, precautions, and other measures used, and address the residual risks, including in the instructions for use[10] in line with risk management framework where risks have been reduced as far as possible.

If achieving the intended lifetime relies on calibration and maintenance or device testing, the manufacturer must provide information within the instructions for use[11] and other technical user documentation, such as the service manual and to characteristics of activities for performance and safety.

For reusable instruments that require cleaning and sterilisation between each use, the manufacturer must specify the cleaning and sterilisation protocol and the number of reuse cycles it can be subject to before disposal.

For implants, the implant card[12] must communicate any information about the expected lifetime of the device and any necessary follow-up.

Many devices have a lifetime defined by the intended purpose and determined through design verification and validation testing. However, it is the manufacturer responsibility to make appropriate claims to the type of device and evidence; for example, a blood pressure monitor could last over ten years if properly maintained. However, the manufacturer may not wish to claim a ten-year lifetime, especially if they only have supporting evidence for two years which may be sufficient for a warranty period. Furthermore, proving that all their blood pressure monitors last ten years may be challenging because it will depend on how well the user looks after and maintains them. In some countries, hospitals may only purchase devices that claim a long lifetime, for example, ten years. So, the manufacturer must consider many factors when determining the lifetime and design of their device. However, within the risk management framework, the lifetime claimed must be specified and supported with appropriate evidence from pre-clinical and clinical/post market phases such as from design, verification, usability, instructional, clinical, and post-market surveillance evaluation evidence, as appropriate for the device.

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8 EN ISO 14971: 2019/A11:2021 Medical devices – Application of risk management to medical devices

9 MDR Annex I, GENERAL SAFETY AND PERFORMANCE REQUIREMENTS, 6.

10 MDR Annex I, 23.4 (s), Indent 1

11 MDR Annex I, 23.4 (k), Indent 3

12 MDR Article 18, 1 (c)

Other sources of lifetime requirements

Safety standards

Some device-specific standards provide lifetime requirements. Therefore, the manufacturer must identify the relevant standards, irrespective of their harmonization status, and consider their lifetime requirements when developing device specifications to state-of-the-art. For example, the medical device electrical safety standard IEC 60601-1[13] requires the manufacturer to state the expected service life in the risk management file and accompanying documents for the organization or operator on basic safety and essential performance. The standard for vascular implants ISO 5840-1[14] requires a mechanical heart valve to operate for 400 million cycles, etc.

Application of appropriate standards and guidance and, if appropriate, other legislative frameworks or guidelines assists in supporting the manufacturer's state-of-the-art claims.

MDCG guidance

Some guidance documents refer to the lifetime, particularly clinical data, communication, and post-market surveillance. For example, MDCG 2019-9[15] requires the Summary of Safety and Clinical Performance (SSCP) to document the device's expected lifetime, including data on implant and survival rates, and MDCG 2020-7[16] requires the manufacturer to disclose the expected lifetime in the PMCF plan.

By following current guidance to the legislation(s), the manufacturer ensures that the consensus interpretation of the MDR legislative framework from the medical device coordination group has been considered, supports the Notified Body assessment process, and assists in demonstrating that the device meets the state-of-the-art requirements.

Other guidance

Some health authorities set expectations for the lifetime of devices. For example, the British National Institute of Clinical Excellence (NICE) requires prostheses for total hip replacement and resurfacing arthroplasty with projected revision rates of 5% or less at ten years[17].

If the manufacturer cannot meet the user's lifetime requirements and prove their device is state-of-the-art, it is unlikely that they will achieve market access or may have market access withdrawn or suspended.

Some organizations may provide guidance to specific device applications, such as clinical guidelines, or provide a uniform approach to the legislative process. For example, Team-NB has published the position paper Medical Device Lifetime[18].

[13] IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety a nd essential performance.

[14] ISO 5840-1: 2021 Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements.

[15] MDCG 2019-9, Rev. 1, Summary of safety and clinical performance, A guide for manufacturers and notified bodies, March 2022.

[16] MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template, A guide for manufacturers and notified bodies, April 2020.

[17] NICE Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip, Technology appraisal guidance (TA304), 26 February 2014

[18] https://www.team-nb.org/wp-content/uploads/2023/12/Team-NB-PositionPaper-Lifetime-Medical-Device-20231127.pdf

Lifetime and device lifecycle

The manufacturer should consider the lifetime requirements throughout the device's lifecycle from conception to the eventual disposal or decommissioning at the end of life. Table 2 summarizes the life cycle steps and lists relevant inputs/outputs to ensure lifetime requirements are met.

Note the below are examples and not an exhaustive list and are dependent on the device.

Table 2: Lifecycle steps to ensure lifetime requirements are met.

Lifecycle steps	Relevant input/output
Conception/Development Establishing the state of the art for the device's lifetime	Risk assessment, market research, benchmarking, post-market data for the device and similar devices, user needs, clinical literature review, guidance documents, standards, health authority requirements, and regulatory requirements.
Development Designing to meet the device's lifetime requirement	Risk assessment, identifying critical components or materials, high integrity components, component deterioration, tolerance analysis, mean time between failures (MTBF) or mean time to failure (MTTF) calculations, highly accelerated life testing (HALT), finite element analysis (FEA), simulated functional testing, security, inter/intra-operability, and device compatibility.
Development Verifying lifetime claims	Risk assessment, life testing (pre-conditioning: sterilization, shipping, shelf life), real-time testing, animal studies, user studies, and clinical trials, cybersecurity testing and monitoring.
Manufacture Production quality controls	Risk assessment, production staff training, process verification, process validation, process controls, environmental controls, and monitoring, burn-in, highly accelerated stress screening (HASS), functional testing, and sample or batch tests.
Service and maintenance	Risk assessment, service personnel training, service and maintenance schedules, the availability of specialist tools, replacement components/parts, software and security updates, calibration, testing, and recommissioning. **Note:** for devices being refurbished additional attention may be needed to determine lifetime of those devices.
Post-market surveillance	Risk assessment, complaints, and vigilance analysis, PMCF studies, ongoing clinical trials, registries, user feedback, service and maintenance records, security and safety updates and clinical evaluation.

Lifetime design tools

As mentioned, the manufacturer should consider lifetime during the development cycle when specifying the device's design requirements. Once specified, the manufacturer can employ several tools to determine and verify the lifetime claims. Design is an iterative process, so early prototypes may not meet lifetime requirements, and design changes may be necessary before the design is frozen. The following sections provide a non-exhaustive list of the tools that the manufacturer can employ.

Component derating and design engineering

Derating is a design process that can significantly contribute to a medical device's reliability and lifetime. Derating is the deliberate policy of under-stressing components to provide increased reliability.

In electronics, derating involves operating components at less than their rated capability to prolong life. Typical examples include the operation of a component below its maximum power, current, or voltage ratings. For example, the design engineer can use a half-watt resistor for an application with a quarter-of-a-watt power dissipation rather than a quarter-watt resistor that would be operating at its design limit.

In mechanical design, components can also be over-engineered to improve reliability. The following options are available to the mechanical design engineer[19]:

a Margin of safety. A larger or reinforced component can carry a higher load than that typically experienced, providing a margin of safety. However, this approach will often increase weight, potentially overstressing other parts of the system. Standards, such as EN/IEC 60601-1 include requirements that provide safety margins. For example, for tensile strength for load-bearing parts where multiplication factors may be applied and to use of high integrity or critical components. Identification of critical materials or components is required as part of the risk-management and evaluation process for performance and safety.

b Improved material characteristics include corrosion resistance, strength (ability to withstand tension, compression, or other forces), toughness (ability to resist cracking or breaking), and hardness. It should be noted that the characteristics that will improve reliability may compete. For example, improving the hardness may result in a lower toughness. Alternative materials that are lighter, stiffer, and stronger can be chosen. However, they may result in higher production costs.

c Redundancy and diversity. The design engineer can use multiple fasteners in dynamic load situations where loosening or fatigue cannot be eliminated. Using multiple fasteners rather than a few larger fasteners allows more precise derating factors to be applied and redundancy measures in the design to protect against failures. Achieving diversity through design options may also have protective outcomes.

d Manufacturing process controls are critical in minimizing component tolerance variations. Closer fitting parts reduce stresses within assemblies as the load is more evenly distributed. Improvement in manufacturing process control is one of the significant factors behind the increased reliability.

e Surface finishes. Surface finish can have a significant impact on fatigue strength for mechanical products. Polished surfaces in a steel structure can provide around 30% improvement to the fatigue strength of a component when compared with a plain machined surface by reducing the number and depth of stress-raising points. Therefore, derating can be obtained using a polished finished item rather than a simple machined finish.

[19] Applied R&M Manual for Defence Systems, Part C R&M Related Techniques.

Tolerance analysis

Tolerance analysis involves understanding how variations in component dimensions or operating characteristics can affect the overall reliability of the design. Tolerance analysis can be applied to electrical/electronic and mechanical systems.

Tolerances can 'stack up' to create worst-case operating conditions, including more significant wear, higher forces, higher heat dissipation, and poorer sealing.

The manufacturer must understand the effects of tolerances on the device's function and overall reliability.

The manufacturer should consider changes in component tolerances as part of the risk management process, (i.e., what happens if the component's characteristics are at the minimum, nominal, and maximum tolerances?)

Mean Time Between Failures (MTBF) and Mean Time to Failure (MTTF)

Mean Time Between Failures (MTBF) is the expected time between two failures on a repairable system. The manufacturer can use the metric to track the availability and reliability of a device. The longer the time between failures, the more reliable the system.

Mean Time to Failure (MTTF) denotes a non-repairable system's expected time to failure.

The manufacturer can make MTBF/MTFF predictions and statistical analyses during development to support the device design for the intended use. Reliability and design engineers can use various methods and standards to predict a system's reliability, for example, MIL-HDBK-217[20].

It should be noted that the MTBF and MTFF calculations result in a mean lifetime (an average value) and do not imply that all devices meet lifetime claims and safety standards for the intended use.

Highly Accelerated Life Testing (HALT)

Highly Accelerated Life Testing (HALT) is a stress testing methodology for enhancing product reliability. Typically, prototypes are stressed to a much higher degree than expected to identify design and manufacturing weaknesses. The device under test is subjected to a combination of temperature and humidity cycling, random vibration, power margining, and power cycling until failure. The manufacturer identifies the root cause of the failure and can implement appropriate design changes. HALT is a test-to-failure methodology that enables the manufacturer to identify and address design weaknesses.

[20] MIL-HDBK-217 Reliability prediction of electronic equipment

Highly Accelerated Stress Screening (HASS)

Highly Accelerated Stress Screening (HASS) is performed while manufacturing products or components. It is a screening process used to expose manufacturing defects that would cause failure in typical field environments, including shipping, storage, and use.

HASS uses a combination of temperature cycling, random vibration, power margining, and power cycling to stress the device or component beyond specification but within the capability of the design.

HASS is typically used when production is established and then reduced as improvements are made, production yields increase, and the product becomes stable, for example, where infantile failures are reduced to acceptable levels.

Finite Element Analysis (FEA)

Finite Element Analysis (FEA) is an analytical tool used to simulate the behavior of a component or assembly under specified conditions. FEA uses mathematical models to understand and quantify the effects of actual-world conditions. It can be used for structural analysis of mechanical components, modeling heat transfer, fluid flow, and electromagnetic phenomena. FEA allows designs to be analyzed before they are manufactured and evaluated. It should be noted that the analysis is only as good as the predictive model, and it is not a substitute for actual testing.

Simulated functional testing

As part of the product development process, the manufacturer can physically simulate the conditions the device will experience to understand its behavior. Simulated functional testing is essential for those devices where real-world testing is challenging before product release. It also allows life testing to be accelerated.

The manufacturer should validate the simulated conditions to demonstrate that they adequately represent real-world conditions.

The manufacturer should develop test protocols that include identifying the units under test and their characteristics (e.g., minimum tolerances, maximum tolerances, etc.), data measurement and analysis plans, and sample size justifications and acceptance criteria.

The manufacturer should conduct simulated testing until the destruction of the device, where practical, to gain complete insight into the device's behavior, support the lifetime claims, and verify the service and maintenance schedules of the device.

Lifetime and device classification

The MDR Annex VIII requires the manufacturer to classify their device to determine the appropriate route to conformity. As part of the classification rationale, the manufacturer must specify the duration of use as follows:

- Transient means normally intended for continuous use for less than 60 minutes
- Short-term means normally intended for continuous use for between 60 minutes and 30 days
- Long-term means normally intended for continuous use for more than 30 days

The manufacturer should not confuse the duration defined in Annex VIII with the lifetime of their device. For example, a cardiac catheter used to cross calcified lesions may be for transient use up to sixty minutes. However, its lifetime may be limited by the number of torsional rotations the device can withstand as the surgeon maneuvers it through the lesion. Similarly, a replacement knee designed for ten years of use is classified as long-term but has a life far exceeding thirty days. The device's lifetime does not necessarily equate to the duration used during classification.

Lifetime and post-market surveillance

The manufacturer can use post-market surveillance safety and performance metrics to verify lifetime claims. For example, the manufacturer can extrapolate lifetime information from maintenance and complaints logs. The manufacturer should take care when using post-market data to calculate a device's lifetime to ensure that it is accurate. A device cannot be considered to have met its lifetime if it has been returned for unscheduled maintenance or repair due to premature failure. The manufacturer must justify the quality of post-market data used to verify lifetime claims to the Notified Body.

The MDR Annex XIV, PART B, 6.1 (a) requires the post-market clinical follow-up plan to specify the methods and procedures for proactively collecting and evaluating clinical data to confirm the safety and performance of the device throughout its expected lifetime. Furthermore, MDCG 2020-7[21] Section B requires the manufacturer to specify the expected lifetime in the PMCF plan.

For Class IIa, Class IIb, and Class III devices, manufacturers must document a Periodic Safety Update Report (PSUR) for each device or, where relevant, for each category or group of devices. The manufacturer must publish PSURs throughout the device's lifetime. MDCG 2022-21 Section 3.2.1 defines the lifetime as the period specified by the manufacturer in the device documentation during which the device is expected to remain safe and effective for use/in use. Section 3.2.2 specifies when the manufacturer's obligation to publish a device's PSUR ends, which is after the last device is placed on the market when the end of the shelf life plus the intended lifetime has been reached.

Valuable post-market data sources for verifying lifetime claims include complaints and vigilance reports, maintenance, service, and repair records, registry data, and the results of long-term clinical studies. The manufacturer may also obtain additional feedback from the sales and distribution process and risk management.

[21] MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template

Summary

The ability of a medical device to be safe and effective for its intended lifetime is a crucial requirement under the MDR. The manufacturer is responsible for specifying their device's lifetime and providing evidence that they meet their lifetime claims.

The manufacturer should establish lifetime requirements based on user needs and the accepted state-of-the-art early in the development cycle and ensure that designs provide the necessary reliability to meet the requirements.

In the post-market phase, manufacturers should monitor for premature device failure and take appropriate corrective and preventative action if a device's lifetime is compromised or unusual part data patterns are observed, such as high demand for replaceable or serviceable parts.

Notified Bodies will assess a manufacturer's technical documentation to find evidence of conformity to the legislative requirements and to confirm that all lifetime-based requirements are met considering the current state-of-the-art, tools, and guidance’s available. Failure to adequately define, declare, and verify a device's lifetime may result in non-conformities, delays, or refusal of CE certification.

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