

Framework conditions and requirements to ensure the technical functional safety of reprocessed medical devices

Rahmenbedingungen und Anforderungen zur Gewährleistung der funktionell-technischen Sicherheit bei der Aufbereitung von Medizinprodukten

Abstract

Testing and restoring technical-functional safety is an essential part of medical device reprocessing. Technical functional tests have to be carried out on the medical device in the course of the validation of reprocessing procedures. These ensure (in addition to the hygiene tests) that the reprocessing procedure is suitable for the medical device. Functional tests are, however, also a part of reprocessing procedures. As a stage in the reprocessing, they ensure for the individual medical device that no damage or other changes limit the performance.

When determining which technical-functional tests are to be carried out, the current technological standard has to be taken into account in the form of product-specific and process-oriented norms. Product-specific norms primarily define safety-relevant requirements. The risk management method described in DIN EN ISO 14971 is the basis for recognising hazards; the likelihood of such hazards arising can be minimised through additional technical-functional tests, which may not yet have been standardised. Risk management is part of a quality management system, which must be bindingly certified for manufacturers and processors of critical medical devices with particularly high processing demands by a body accredited by the competent authority.

Keywords: functional safety of reprocessed medical devices, functional testing, risk management, validation of reprocessing

Zusammenfassung

Die Prüfung und Wiederherstellung der technisch-funktionellen Sicherheit ist ein wesentlicher Bestandteil der Aufbereitung von Medizinprodukten. Im Rahmen der Validierung von Aufbereitungsverfahren müssen technisch-funktionelle Prüfungen am Medizinprodukt erfolgen. Sie stellen (neben den hygienischen Untersuchungen) sicher, dass der Aufbereitungsprozess für das Medizinprodukt geeignet ist. Funktionsprüfungen sind jedoch auch ein Bestandteil von Aufbereitungsprozessen. Sie gewährleisten als Aufbereitungsschritt für das einzelne Medizinprodukt, dass keine Beschädigungen bzw. andere Veränderungen die Leistungsfähigkeit einschränken.

Bei der Festlegung durchzuführender technisch-funktioneller Prüfungen ist der Stand der Technik in Form produktspezifischer und prozessorientierter Normen zu berücksichtigen. Produktspezifische Normen definieren vorrangig sicherheitsrelevante Anforderungen. Die in der Norm DIN EN ISO 14971 beschriebenen Methodik des Risikomanagements ist die Grundlage für das Erkennen von Gefährdungen, deren Auftretenswahrscheinlichkeit durch ergänzende, bisher ggf. nicht genormte technisch-funktionelle Prüfungen verringert werden kann. Das Risikomanagement ist Teil eines Qualitätsmanagementsystems, welches verbindlich für Hersteller und Aufbereiter von kritischen Medizinprodukten mit

Marc Kraft¹

1 Technische Universität Berlin,
Department of Medical
Technology, Berlin, Germany

besonders hohen Anforderungen an die Aufbereitung durch eine von der zuständigen Behörde akkreditierte Stelle zertifiziert sein muss.

Schlüsselwörter: funktionelle Sicherheit aufbereiteter Medizinprodukte, funktionelle Prüfung, Risikomanagement, Validierung der Aufbereitung

Framework conditions and requirements to ensure the technical functional safety of reprocessed medical devices

The term “reprocessing” is defined in § 3 para. 14 of the German Medical Devices Act (*Gesetz über Medizinprodukte*, hereinafter MPG) as follows: The reprocessing of medical devices that, pursuant to their specifications, are to be applied semi-sterile or sterile, is the cleaning, disinfection and sterilisation (including the processes involved herein) as well as the examination and restoration of technical-functional safety following their use, for the purposes of repeated use.

Reprocessing encompasses cleaning, disinfection and sterilisation, including the processes connected therewith, as well as the **testing and restoration of technical-functional safety**. While the former processes aim to exclude hygienic risks, testing and restoring the technical functional safety guarantees the exclusion of hazards that could arise from altered characteristics of reprocessed medical devices. The German Ordinance on the Construction, Operation and Use of Medical Devices (*Medizin-Produkte-Betreiber-Verordnung*, hereinafter MPBetreibV) provides in § 4 ‘Maintenance’ that: “The reprocessing of medical devices that, according to their purpose, are to be applied semi-sterile or sterile, is to be carried out taking into account the manufacturer’s specifications using a suitable validated procedure, so that the success of this procedure can be verifiably ensured and the safety and health of patients, operators or third parties is not put at risk”. This requirement also refers indirectly to technical tests, because the success of the procedure, or, as the case may be, the exclusion of hazards connected therewith, can only be verifiably proven if, in addition to hygienic safety tests, the functional and application characteristics of reprocessed medical devices are also tested. Medical devices must fulfil their purpose without limitation during each use, regardless of how many times they are used. In order to comply with the basic principle of the free movement of goods, services and capital, the Member States of the European Community also issued various directives on medical devices. The “basic requirements for medical devices” are set forth in Annex I to Directive 93/42/EEC concerning medical devices. These provisions were transposed into German national statutory provisions without alteration (MPG § 7 ‘Basic Requirements’). The directive 93/42/EEC is not applicable for: active implantable medical devices (90/385/EEC), in-vitro-diagnostics (98/79/EEC) and medical devices that contain stable derivatives of human blood or blood plasma (2000/07/EEC).

Several of the requirements set forth in Directive 93/42/EEC [3] relate to medical devices intended by the manufacturer to be used repeatedly. Accordingly, Art. 13.6 of Annex I requires that the directions for use state “details concerning suitable processing procedures, e.g. cleaning, disinfection, packaging and, where applicable, sterilisation procedures ... as well as information on any limit to the number of times it can be reused ...”, thereby placing the responsibility for the selection and suitability of the reprocessing procedures for these products (including the requisite technical-functional tests) on the manufacturer. In addition to these medical devices and medical devices which are not suitable for reprocessing due to, for example, their construction, on technical, material grounds or on the basis of hygiene-related or ethical reasons, there is also a group of products for which the manufacturers do not state any reprocessing procedure, but for which it has been proven that they can be reprocessed with suitable procedures that can be validated (pursuant to § 4 MPBetreibV).

Despite the fact that, to date, Directive 93/42/EEC does not contain any stipulations specifically governing these medical devices (national interests and statutory framework conditions of the Member States vary considerably), the ‘basic requirements’ also apply to them. Thus, Art. 3 of Annex I requires that: “The devices must achieve the performances intended by the manufacturer...” This applies for each use of a medical device, regardless of the number of completed applications or the issue of initial market authorisation. The conformity of a reprocessed medical device with the basic requirements may not be altered, even if a new conformity assessment procedure is not necessary, provided there is no new incidence of the product being placed on the market. The achievement of the “intended performance” is ensured if the medical device fulfils its intended use without limitations in terms of the stated quality and required safety for the patient, for the user or for third parties. In the case of medical devices that the manufacturer does not intend to be re-used, the suitability of a reprocessing procedure (which can be validated) is given only if the functionality can also be proven in terms of technical-functional tests. The costs of the tests necessary in this connection can vary greatly. Which tests are necessary depends *inter alia* on the complexity of the medical device, the style of construction, the raw materials used, the area of application, the duration of the application, the reprocessing procedure and – perhaps most importantly – on the risk potential of the medical device, and must (as explained below) be determined according to the individual product in the course of the development and validation of a reprocessing procedure.

Pursuant to the Medical Devices Operators Ordinance (MPBetreibV) proper reprocessing is assumed, “if the joint recommendation of the Commission for Hospital Hygiene and the Prevention of Infection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) concerning the hygiene requirements when processing medical devices is observed” [1]. This guideline recommends that the validation of a reprocessing procedure should be proportionate to the medical device, to “the risk evaluation and categorisation”, and should be carried out “in accordance with the accepted rules of technology, taking into account the current scientific and technological standards”. The design parameters of the medical device to ensure the **technical-functional safety** (suitability of the procedure for the medical device) “that are necessary to prove that the process in question (individual stage of processing) is carried out in a form that guarantees the attainment of the specifications defined in each case”, are also stated, in addition to the parameters for ensuring “effective cleaning, disinfection and sterilisation”. Thus, technical-functional tests must also be carried out in the course of the validation of reprocessing procedures. These ensure (in addition to the hygiene tests) that the reprocessing procedure is suitable for the medical device. These technical-functional tests in the course of the validation of reprocessing procedures are usually carried out in the form of random tests, such that characteristics critical for the success of reprocessed medical devices can be compared with the corresponding parameters of new products. The product characteristics to be tested are selected, as explained below, as part of the risk management.

Furthermore, the aforementioned RKI and BfArM guideline [1] also stipulates the individual reprocessing stages. In addition to cleaning/disinfection, rinsing and drying, and other additional steps, this usually also includes **functional tests**. These exclude the possibility for the individual medical device that damage or, as the case may be, other changes, limit the functionality, although proof of the theoretical suitability of the procedure used was already provided in the course of the validation of the reprocessing procedure. This is necessary because individual or coincidental effects (e.g. when the device is used incorrectly or the necessary transport conditions are not observed) can also constitute hazards when using reprocessed medical devices and, consequently, the affected products cannot be used again. In this regard, the RKI and BfArM guideline [1] states: “The objective of the tests on ... defined technical-functional characteristics is to sort out medical devices in which ... technical-functional defects cannot be removed.” The scope and the cost of the functional tests that constitute part of the reprocessing procedure is often lower than that of the functional tests that are relevant to the validation. This is due to the option of being able to limit these tests to those product attributes that are relevant to the safety and that can be affected by individual or coincidental effects. These tests are usually carried out after cleaning/disin-

fection, rinsing and drying, in order to be able to record any possible negative effects of these reprocessing stages on the medical device as well. In the case of medical devices to be applied semi-sterile or sterile, however, recontamination through the test substances must be excluded. The RKI and BfArM guideline [1] requires that: “contamination with harmful substances (e.g. toxic cleaning materials) or particles (e.g. talcum) that outlive the following stages of reprocessing may not occur.”

When determining or selecting the necessary functional tests to be carried out on reprocessed medical devices, the manufacturer or processor, as explained above, must take into account the current scientific and technological standards. Studies with the highest possible level of evidence and recognised publications substantiate the current scientific standard. The current technological standard is documented mainly through norms and recognised standards. Accordingly, § 8 para. 1 of the Medical Devices Act (MPG) states: “if medical devices comply with harmonised norms or equivalent monographies of the European Pharmacopoeia or Joint Technical Specifications that apply to the medical device in question, it shall to this extent be assumed that these comply with the provisions of this Act.” Both product-specific and process-oriented norms are relevant, in particular with regard to quality management and risk management, as well as the procedures applied in the reprocessing (among others cleaning, disinfection, sterilisation, electrical, biological tests which contains a detailed list of relevant norms [2]). Product-specific norms primarily define requirements that are relevant to safety. For example, ISO 10555-4 [3] specifies for balloon catheters: tests of the surface finish, resistance to corrosion, tensile strength, leakage rate, x-ray visibility, surface structure and resistance to bursting of the catheter balloon (fatigue). These tests are relevant to the safety and, as a result, are to be taken into account in the course of the validation of the reprocessing procedure carried out on medical devices. However, they are informative only to a very limited extent with regard to the characteristics of the product in question that are relevant to its application and, even where all test requirements are met, they do not allow any conclusions to be drawn as to the degree of suitability of a medical device for its application (e.g. for balloon catheters the suitability of the balloon for relief of vaso-constriction). Consequently, additional functional tests may have to be carried out. As the balloon catheter example clarifies, these tests are, for example, tests on the internal-pressure-dependent diameter of the balloon as well as the inflation and deflation times. Although these kinds of tests are not standardised for balloon catheters, these are parameters that are critical to success and it is obvious that these have to be tested in order to exclude any hazards. The RKI and BfArM also state in their guideline [1] that effects of the reprocessing procedure on the material characteristics and on the technical-functional safety are, as a rule, product-specific and therefore have to be examined in each individual case.

Testing requirements of this kind for any given medical device must, in the interests of full and systematic recording, be developed using the method described in DIN EN ISO 149715 [4]. The risk management outlined in this norm encompasses the analysis, the evaluation and the control of the risk initially ascertained by way of risk-reduction measures, as well as the re-evaluation, following completion of these measures. Risk analyses are also part of the technical documentation for medical devices and are important for the declaration of conformity and the CE-mark when fulfilling the basic requirements for placing new products on the market.

The first stage in risk management pursuant to DIN EN ISO 14971 [6] is the hazard analysis, in which all potential sources of harm, which may arise both in the case of proper and improper use of the medical device, are ascertained. Every function of the medical device is examined in terms of reasonably expected consequences of events that could lead to harm for the most diverse use situations. For each ascertained hazard, the risk must be determined by estimating the likelihood of it occurring and the potential extent of the damage. Among others, the risks named in the RKI and BfArM guideline [1], which can arise through

- residues from the preceding application (e.g. blood, blood components, secretions and other bodily components, other medicinal products),
- residues from the preceding processing procedure (e.g. substances used in cleaning, disinfection, and sterilisation, as well as other materials, including reaction products thereof),
- changes to the physical, chemical or functional characteristics of the medical device or
- changes to the condition of the material (e.g. accelerated wearing of the material, embrittlement and altered surface characteristics, changes to contact points and adhesive bonding).

are to be taken into account.

Usually, the ascertained risk is allocated to a class of risk. Acceptable risks can, compared with the benefits, be disregarded. Unacceptable risks are so serious that a system involving these risks would be untenable. They must be reduced by limiting the extent of the damage and/or the likelihood of the hazard occurring. The latter can be achieved, for example, through tests that reveal negative divergent product characteristics. Necessary tests, which have not yet been standardised (standardised tests document, as explained above, the current technical standard and are in any case relevant), are therefore specified as risk reduction measures in the course of risk management.

However, it is not possible to estimate for every medical device used over a longer period of time, the damage caused by, or the likelihood of all potential events that may shorten its lifespan on the basis of theoretical analysis. This is why, in specific cases, these are to be underpinned by relatively expensive mechanical tests, which effect “artificial ageing” in terms of simulated use and

processing and provide statistically representative proof that it is possible to use the medical device repeatedly, without technical-functional limitations. Precise knowledge of the operational demands that are typical of the usage is necessary in order to carry out tests of this kind. It is also important that the tests are carried out on new products (without prior damages). The scope of the random tests should be as broad as possible, because then the coincidental differences between the results of the random test and the actual conditions in the target population are smaller. Subject to known or expected marginal conditions (standard divergence, selectivity and expected relative difference) the size of the random test, which is dependent on the test procedure, can be calculated.

Risk management is part of a quality management system, which must be bindingly certified for manufacturers and processors of critical medical devices with particularly high processing demands by a body accredited by the competent authority pursuant to DIN EN ISO13485 [5] (see [1]). The base for the risk management is the classification pursuant to the recommendation of the Commission for Hospital Hygiene and the prevention of Infection at the Robert Koch-Institute (RKI) and the Federal Institute for Medicinal Products and medical devices (BfArM) regarding the hygiene requirements when processing medical devices [1].

The reproducibility of the results of the processing necessary for validation can only be attained through the compliance with and constant monitoring of all process parameters in the processing stages. This is the only way that the proof of the theoretical suitability of a processing procedure established by way of technical-functional tests and other tests for a medical device can be transferred to all subsequent applications of the procedure. Reproducible process parameters are ensured when using cleaning/disinfection equipment by way of corresponding process monitoring (see DIN EN ISO 15883 washing and disinfection of instruments), while manual procedures always entail greater risks. The RKI and BfArM guideline [1] states in this connection: “in mechanical cleaning and disinfection procedures it can be ensured in terms of the process that the parameters necessary to attain quantifiable cleaning and disinfection performance, e.g. water volume, water pressure, temperature, pH-level, dosage of cleaning and disinfection substances and contact time, are observed. The machines’ monitoring, control and warning systems constitute the prerequisite for secure cleaning and disinfection and, thus, reprocessing”. Pursuant to the classification of medical devices on the basis of their hazard potential, which is set forth in the guideline [1], mechanical cleaning and disinfection is already the preferred method for semi-critical medical devices with more stringent requirements in terms of the reprocessing (e.g. gastroscopes) and for critical medical devices without special requirements in terms of the reprocessing (e.g. wound retractors). For critical medical devices with more stringent processing requirements (e.g. MIS trocars) mechanical cleaning and disinfection is generally required

for all parts with direct tissue contact or for critical medical devices with particularly stringent processing requirements [1].

6. DIN EN ISO 15883-1 Washer-disinfectors - Part 1: General requirements, definitions and tests (ISO 15883-1:2006); German Version EN ISO 15883-1:2006.

References

1. Recommendation of the Commission for Hospital Hygiene and the Prevention of Infection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Products (BfArM) regarding the "hygiene requirements when processing medical devices". Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2001;44:1115-26.
2. Klosz K. Qualitätsmanagement für die Aufbereitung von medical devices. In: Kramer A, Assadian O, Surber C, editors. Wallhäusers Praxis der Sterilisation, Desinfektion, Antiseptik and Konservierung - Qualitätssicherung der Hygiene in industriellen und medizinischen Bereichen. Stuttgart: Thieme; 2008 [in print].
3. DIN EN ISO 10555-4, sterile, single-use intravascular catheters - Part 4: Balloon dilatation catheters (ISO 10555-4:1996); German Version EN ISO 10555:1997.
4. DIN EN ISO 14971, risk management for medical devices (ISO 14971:2000); German Version EN ISO 14971:2000 and ISO 14971 risk management for medical devices 2007-03.
5. DIN EN ISO 13485 Medical devices - Quality management system requirements for Regulatory purposes (ISO 13485:2003); German Version EN ISO 13485:2003.

Corresponding author:

Prof. Dr.-Ing. Marc Kraft
Technische Universität Berlin, Fachgebiet Medizintechnik,
Institut für Konstruktion, Mikro- und Medizintechnik
"Sicherheit und Effektivität aufbereiteter
Medizinprodukte", Dovesstraße 6, 10587 Berlin, Germany
marc.kraft@tu-berlin.de

Please cite as

Kraft M. Framework conditions and requirements to ensure the technical functional safety of reprocessed medical devices. *GMS Krankenhaushyg Interdiszip.* 2008;3(3):Doc23.

This article is freely available from

<http://www.egms.de/en/journals/dgkh/2008-3/dgkh000121.shtml>

Copyright

©2008 Kraft. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by-nc-nd/3.0/deed.en>). You are free: to Share – to copy, distribute and transmit the work, provided the original author and source are credited.