Reusable medical devices

Testing, classification, benefits

Add value.
Inspire trust.

What is reusable device testing for medical devices?

Reusable device testing refers to the process of verifying and validating IFUs regarding the cleaning, disinfection and sterilization of reusable medical devices to ensure their safety, efficacy and performance.

Reusable medical devices

Importance of reusable device testing

Reusable medical devices test plays a key role in patient care by providing cost-effective and sustainable solutions for healthcare providers.

However, reusable medical devices must be accompanied by instructions detailing the cleaning/disinfection/sterilization process to ensure that risks of transmission of infectious agents are minimized.

Validation of the reprocessing process helps manufacturers ensure compliance with industry regulations, reducing harm to patients and maintaining their reputation in the industry.

Reusable medical devices

Reusable medical devices are designated or intended by the medical device manufacturer as suitable for processing and reuse.

Examples of reusable medical devices

surgical instruments

endoscopes

respiratory devices

And others. Devices that are single use (orthopedic implants) that need to be processed prior to first use, are included in the classification of reprocessing.

Classification of medical devices

In reprocessing, medical devices are classified based on the criticality of the device:

Non-critical Devices

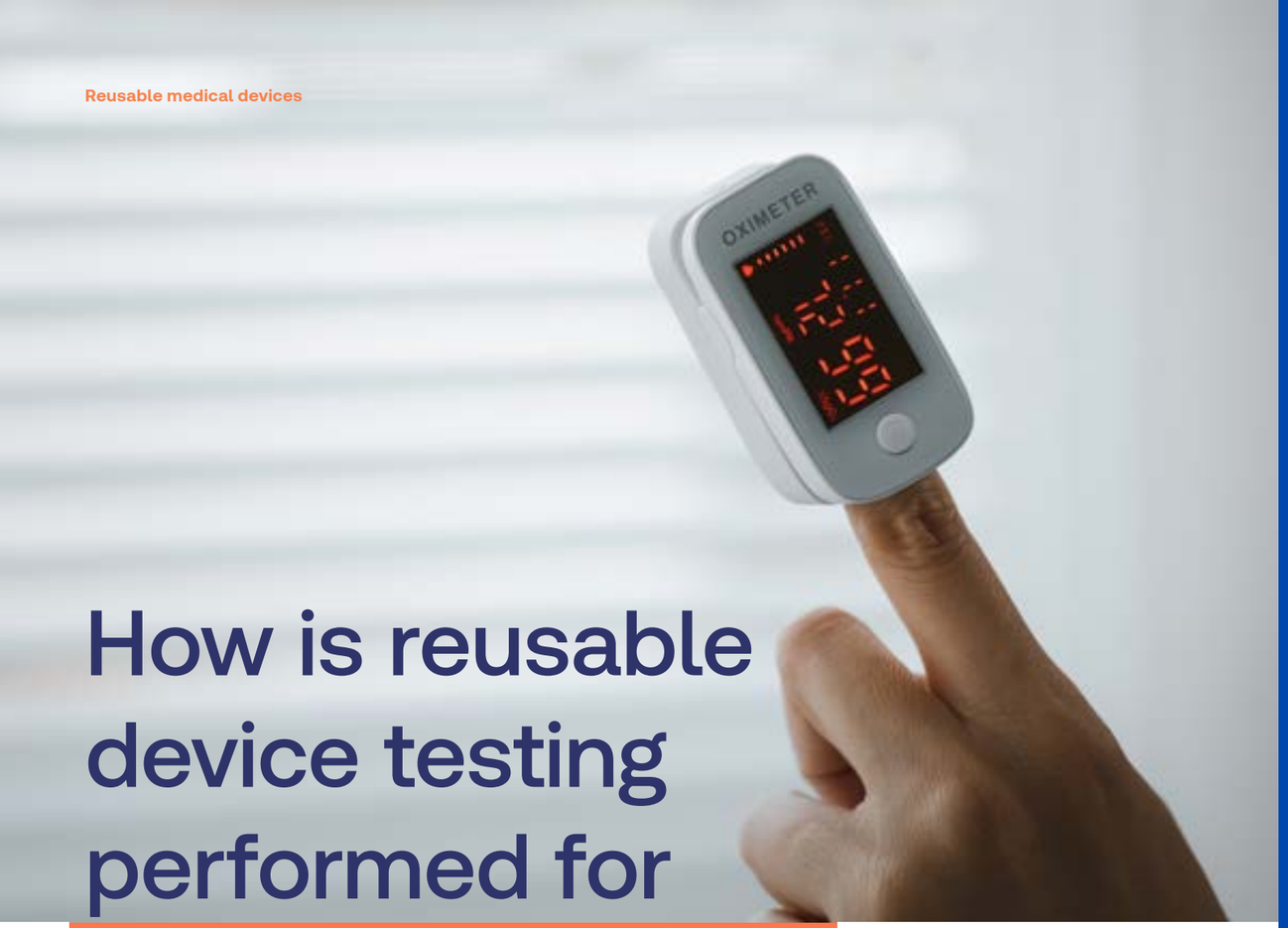
Intact skin, no penetration, or non-direct patient contacting (e.g., ultrasound probes, wearable devices)

Semi-critical Devices

Mucosal membranes or non-intact skin (e.g., dental devices that go into the oral cavity)

Critical Devices

Bloodstream or sterile cavities (e.g., surgical instruments)



How is reusable device testing performed for medical devices?

Manufacturers of reusable devices must provide detailed instructions for use (IFUs) that include information on recommended cleaning/disinfection/sterilization procedures, adhering to appropriate standards and regional guidelines that require appropriate instructions for use on the label of the medical device that has been thoroughly validated.
IFUs should be clear, understandable, and concise and should be available in the accepted languages in the member states where the device is intended to be sold.

1 Reprocessing validation

Involves performing the tests identified by the manufacturer, depending on the type of medical device produced and its intended use.

Some of the most common tests

Cleaning validation

Ensures that the device can be properly cleaned between uses to prevent contaminant buildup. Verification of the cleaning process can be performed manually or automatically, according to the manufacturer's IFU; performed by visual inspection and/or detection of selected analytes (e.g., protein residues using the Bradford test, Total Organic Carbon). The medical device cleaning validation procedure consists of the following steps:

Running at least **six simulated cycles**.	**Soiling (use simulation)** Application of a test soil suitable for the use characteristics of the medical device.	**Cleaning** Manual or automatic removal of residues of the test medium applied in the previous step. The customer's protocol is applied.	**Extraction** Extraction of residues of the test medium after cleaning.

Sterilisation and drying validation

Ensure that the device can be effectively sterilized between uses to render the device free from microorganisms. The procedure for validating the sterilization of the medical device consists of the following steps:

Inoculum (simulation of use) Inoculate the device with a known amount of a specific microorganism or include biological indicators in strips in the package.	**Sterilization** Sterilize the device according to the customer's protocol (e.g. autoclave sterilization).	**Sterility test** By immersion in TSB under laminar flow hood.

Disinfection validation

Ensures that the device can be adequately disinfected between uses to reduce the defined number of viable organisms. Verification of the disinfection process can be performed manually or automatically, according to the manufacturer‘s IFU. The level of disinfection depends on the criticality of the Medical Device and involves the inoculation of specific microorganisms.
The procedure for validating the disinfection of the medical device consists of the following steps:

Inoculum (simulation of use)
Deposition of microorganisms on the medical device.

Disinfection (disinfection procedure)
Manual or automatic elimination of the microorganisms applied in the previous step. The customer’s protocol is applied.

Extraction
Extraction of residual viable microorganisms after disinfection activity. Subsequently, the recovery test of the inoculated microorganisms is performed, and the logarithmic results of the bacterial load are used.

According to AAMI TIR12, three levels of disinfection can be performed: Low, Intermediate and/or High-level disinfection. Each kind of disinfection requires to use different microorganisms:

Acceptance criteria for a low-level disinfection
Are 6-log reduction of typical vegetative organisms, such as Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, and representatives of the Klebsiella-Enterobacter group.

Acceptance criteria for intermediate-level disinfection
Are 6-log reduction of typical vegetative organisms, including Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, and representatives of the Klebsiella-Enterobacter group, and at least 3-log reduction of an appropriate Mycobacterium species.

The acceptance criterion for high-level disinfection
Is 6-log reduction of an appropriate Mycobacterium species.

Life-cycle testing

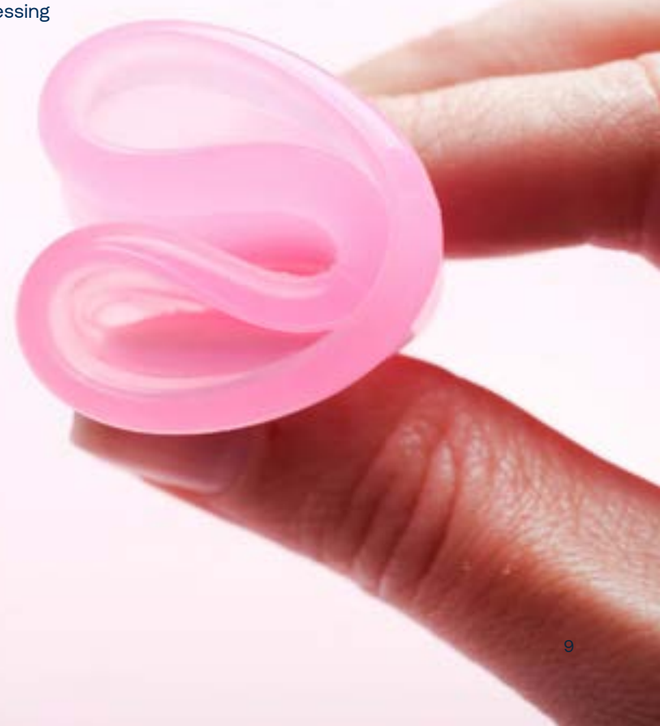
Subjecting the device to the number of processing cycles defined by the Manufacturer to remain safe and functional for its intended use.

Functionality testing

Ensures that the device meets the performance requirements specified by the manufacturer, after repeated reprocessing of the device.

Biocompatibility testing

Ensures that the device materials and any remaining residues from reprocessing activities are not toxic or harmful to the human body. Takes into consideration the life cycle of the device to ensure that the device materials are safe after repeated reprocessing



How pH Labs can support manufacturers of reusable devices

pH Labs supports reusable medical device manufacturers in the validation of reprocessing activities defined by the Client by performing cleaning, disinfection, and sterilization validation tests under ISO/IEC 17025 accreditation, also supporting the customer through the life cycle and subsequent device safety evaluations. All instruments used during analysis are subject to inspection in accordance with regulations.

pH s.r.l. is accredited by ACCREDIA (LAB N° 0069 L) for testing activities according to standard UNI CEI EN ISO/IEC 17025:2018. The accreditation is evidence of professional and technical competence of our laboratory regarding the accredited tests and the conformity to the standard UNI CEI EN ISO/IEC 17025. pH s.r.l. also has Good Laboratory Practice (GLP) certification.

Reusable medical devices

Benefits of reusable medical device testing

Reusable devices must be subject to regulatory testing in order to ensure greater patient safety and improve overall efficiency in the medical industry.

Following the associated benefits in more detail:

1. Ensuring patient safety

Reusable medical device validation helps to ensure that devices are safe for patients to use, reducing the risk of harm or injury.

2. Improving infection control

Proper cleaning and sterilisation of reusable devices is critical for preventing the spread of infections in healthcare settings. Reusable device testing helps to ensure that devices can be effectively cleaned, disinfected, and sterilized between uses.

3. Meeting regulatory requirements

In most regulatory markets, reusable device testing is a mandatory requirement to comply with the local regulations (e.g. MDR).

4. Enhancing device performance

Reusable device testing may help to identify any issues with device performance related to reprocessing, allowing manufacturers to make improvements and enhance device functionality.

5. Cost-effectiveness

Reusable medical devices are often more cost-effective than single-use devices. By conducting proper testing and cleaning validation for medical devices, it becomes possible that these devices can be safely and effectively used multiple times, reducing overall costs.

6. Sustainability

Reusable medical devices are also more sustainable than single-use devices, as they generate less waste. Proper testing and validation can help to ensure that these devices are safe and effective for repeated use, promoting sustainability.

Contact us

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