

WFHSS Guidelines

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WFHSS guidelines - Outline

- **WFHSS missions – key words**
- **WFHSS and national societies**
- **Today practices**
- **Challenges**
- **WFHSS guidelines**
- **Conclusion**



WFHSS missions – Key words

Reusable Medical Devices (RMD)

***Hospita
Is World***

Reprocessing

Science

Federation

Education

Recommendations



WFHSS Federation of National societies

*National
societies*

National Regulators

Local industrial & service partners

*National Medical, surgery, nurse
societies*

National infection control societies

WFHSS

Regulators

International industrial & service partners

World medical and surgery societies

Infection control



Many guidelines

National

Habits/science?

Disparities/similarities



Challenges



Framework for

*Education and improved practices
across the world*

Science and innovation

**Dialogue with regulators, industrial
partners, care societies, infection
control**

Adapt to changes



Global vision of the reprocessing

Educative format but not training

Review of practices, standard, regulation

Different levels of reading



WFHSS Guidelines – how?

Interactive/ Digital but printable

Free access directly to website or
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In english + Google translation



WFHSS Guidelines – how to make the best of it

*recommendations but no conflicts with regulation,
standards and local guidelines*

Food for thought

Evolutionary - feedbacks







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Human Resources

Quality Management

Reusable Medical Device

Point of use processing

Cleaning & Disinfection

Controls & Assembly

Packaging

Transport

Sterilization



World Federation of
Hospital Sterilization Societies

Guidelines

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— Belgium

-  Good practices for the sterilisation of medical devices – 2017 – Superior Health Council
-  Good practices voor sterilisatie van medische hulpmiddelen – Herziening van de aanbevelingen voor sterilisatie – 2017 – Hoge Gezondheidsraad
-  Bonnes pratiques en matière de stérilisation des dispositifs médicaux – 2018 – Conseil Supérieur de la Santé



Links

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Institutional and industrial
partners

Regulation & Standards

Human Resources

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Guidelines

Cleaning & Disinfection

Objectives of cleaning and disinfection

Cleaning is intended to **remove matters** (e.g., patient secretion and inorganic material such as salts) from surfaces of **reusable medical devices (RMD)**

Disinfection, is intended to **reduce the microbial load**

- Cleaning, disinfection or both take place in preparation for **sterilization**. Or with disinfection may be a final step before use of an RMD.
Before **sterilization**, the primary objective is cleaning i.e. the withdrawal of matter that would interfere with a sterilizing agent and generate **endotoxin** or **pyrogen** risks. Disinfection improves the preparation of an RMD for sterilization and is required or recommended in some countries as an **occupational health and safety** measure for operators in charge of **packaging**.
- As the **last step before use of and RMD**, the objective of cleaning and disinfection is to render the RMD safe for the patient according to **Spaulding classification** principles.

Cleaning and disinfection takes place after the **point of use processing** and disassembly of multicomponent RMD

Although cleaning and disinfection are different in practice, they are often grouped in a cleaning and disinfection process (e.g., automated washer disinfection). Therefore they were grouped together in a single chapter of these guidelines

Principles of cleaning

Cleaning consists of **washing** followed by **rinsing**

- **Washing** is using water that contains a cleaning agent to remove soils from RMD surfaces.
- **Rinsing** clears the soils removed by washing as well as cleaning agent residues which would chemically interact with disinfection or sterilization agents.

Main categories of detergent are : (1) neutral with or without enzymes, (2) mild alkaline with or without enzymes, (3) alkaline

Cleaning is performed according to the **manufacturers's IFU's (instructions for use) of an RMD, cleaning equipment and cleaning**.

Consistency of cleaning (i.e. regular application of a cleaning procedure after each use of an RMD) is key to avoid the progressive formation of **biofilm** or build-up of **mineral deposits** in narrow spaces or cavities

Principles of disinfection

Disinfection is **chemical or thermal**

1. **Chemical disinfection** with a disinfectant or cleaning and disinfectant formulation is followed by **rinsing, drying** and when recommended by an RMD IFU, by **lubrication**.

Chemical disinfection is used for thermosensitive RMD's. An RMD is immersed in a bath (using a manual process), exposed to spray (using an automated process) or wiped (used only when immersion or spray



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Washer-disinfector (WD)

Automated endoscope reprocessor (AER)

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Cleaning & disinfection flowchart

g & Disinfection

cleaning and disinfection

to **remove matters** (e.g., patient secretion and inorganic material (e.g., salts) from surfaces of **reusable medical devices** in order to **reduce the microbial load**

Disinfection takes place in preparation for **sterilization** or with disinfection as a final step before use of the RMD.

Cleaning, the primary objective is cleaning i.e. the withdrawal of matter which would interfere with the sterilizing agent. Cleaning is a prerequisite for the preparation of RMD for sterilization and is required or recommended in some countries as an **occupational health and safety measure**.

Before use of the RMD, the objective of cleaning & disinfection is to render the RMD safe for the patient according to the requirements of the **point of use processing**.

Cleaning takes place after **point of use processing** and disassembly of multicomponent RMD

In objectives, cleaning and disinfection are, in practice, often grouped in a cleaning&disinfection process (for more details see the chapter of present guidelines)

Cleaning

washing followed by rinsing

removal of soils from surfaces of the RMD by water containing a cleaning agent.

removes the soils detached by washing as well as detergent residues which would chemically interact with disinfectants

Detergent are : neutral, with or without enzymes, mild alkaline with or without enzymes, alkaline

should be used according to **instructions for use of RMD, cleaning equipment and cleaning agent manufacturers**

Links to chapters

Sterilization

Sterilization is intended to render the reusable medical device free from viable microorganisms. Sterilization is implemented on a clean RMD. Most common Sterilization process is steam. Low temperature sterilization processes are available for heat sensitive RMD

[Go to sterilization chapter](#)

Disinfection is **chemical** or **thermal**

1. **Chemical disinfection** with a disinfectant or cleaning

Chemical disinfection is used for thermosensitive RMD's. An RMD is immersed in a bath (using a manual process), exposed to spray (using an automated process) or wiped (use RMD manufacturer's IFU).

Chemical disinfection is achieved when all RMD surfaces have been exposed to the disinfecting formulation at concentration, temperature and for the contact time specified by the manufacturer. Disinfection is characterized by the achievement of a specified **log₁₀ reduction** of representative test microorganisms (unlike **sterilization** which targets eradication of all microorganisms).

Chemical disinfectants formulations are peracetic acid or aldehydes (Glutaraldehyde, Ortho-phthalaldehyde-OPA). Detergent-disinfectants use chemical with dual properties of cleaning and disinfection.

Choice of disinfectant is made in partnership with **infection control**. Disinfectant must be effective on the type and quantity of microorganisms that may be present on an RMD.

A manufacturer of a chemical washer-disinfector, defines periodicity and a method for self-disinfection of the chemical WD. The objective of self-disinfection is to eliminate contamination. Self-disinfection can be thermal (i.e., hot water) or chemical. If chemical, local guidelines may require a disinfectant different from the one used for reprocessing cycles.

2. **Thermal disinfection** is performed in automated washer-disinfectors (WD) with hot water at specified temperature. Thermal disinfection is commonly used for surgical instrument reprocessing.

Reusable containers and other heat and moisture compatible items are also thermally disinfected. WD disinfection and rinsing are combined in thermal disinfection. Thermal disinfection is also efficient for self-disinfection of the washer-disinfector.

Manufacturers of thermal WD may however offer or recommend periodic self-disinfection cycles.

Thermal disinfection, is achieved when all RMD surfaces have been exposed to hot water at a defined temperature for a minimum contact time. Thermal disinfection is efficient to eliminate most microorganisms. Spores show higher resistance. Thermal disinfection can be characterized by the **A₀ concept**.

Even after disinfection, an RMD may still carry some microorganisms and residual humidity and there are not protected by **packaging**. Precaution must be taken to limit environmental contamination. Maximum **storage** time after disinfection are usually defined by local guidelines or regulations.

Choice of cleaning & disinfection process

The **4 main categories** of cleaning and disinfection processes are

1. **Manual cleaning and disinfection**. RMD's are immersed and manually processed in cleaning and then disinfection baths, or in combined cleaning and disinfection solutions. When using a manufacturer's IFU, an RMD is wiped off.
2. **Automated washer disinfector** (for surgery and dentistry RMD's). Disinfection is thermal or chemical.
3. **Ultrasonic cleaning**, when approved, according to an RMD manufacturer IFU,
4. **Automated Endoscope Reprocessors (AER)** for thermosensitive flexible endoscopes

The **Choice** of cleaning and disinfection process, cleaning, disinfection and lubrication agents go by the RMD manufacturer's IFU, and detergent as well as cleaning equipment manufacturer's recommendations.

Direct access to paragraphs

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Principles of disinfection

Disinfection is **chemical** or **thermal**

1. **Chemical disinfection** with a disinfectant or cleaning and disinfectant formulation is followed by **rinsing**, **drying** and when recommended by an RMD IFU, by **lubrication**.

Chemical disinfection is used for thermosensitive RMD's. An RMD is immersed in a bath (using a manual process), exposed to a disinfectant formulation or wiped with a disinfectant when immersion is not allowed according to an RMD manufacturer's IFU).

Chemical disinfection is achieved when all RMD surfaces have been exposed to the disinfecting formulation at concentration, temperature and for the contact time specified by the disinfectant manufacturer's IFU. Disinfection is characterized by the achievement of a specified **log₁₀ reduction** of representative test microorganisms (unlike sterilization which targets eradication of all microorganisms).

Chemical disinfectants formulations are peracetic acid or aldehydes (Glutaraldehyde, Ortho-phthalaldehyde-OPA). Detergent-disinfectants use chemical with dual properties or mixtures of detergent and disinfectant

Choice of disinfectant is made in partnership with **infection control**. Disinfectant must be effective on the type and quantity of microorganisms that may be present on an RMD.

A manufacturer of a chemical washer-disinfector, defined periodicity and a method for self-disinfection of the chemical WD. The objective of self-disinfection is to eliminate contaminants that may have accumulated over time within the WD. Self-disinfection can be thermal (i.e., hot water) or chemical. If chemical, local guidelines may require a disinfectant different from the one used for reprocessing cycles.

2. **Thermal disinfection** is performed in automated washer-disinfectors (WD) with hot water at specified temperature. Thermal disinfection is commonly used for surgical instruments intended for steam sterilization. **Lubrication** is applied as recommended by RMD manufacturer IFU.
Reusable containers and other heat and moisture compatible items are also thermally disinfected. WD disinfection and rinsing are combined in thermal disinfection. Thermal disinfection provides good **drying**. A **rinse aid** may be added to the rinse water. Thermal disinfection is also efficient for self-disinfection of the washer-disinfector.

Manufacturers of thermal WD may however offer or recommend periodic self-disinfection cycles

Thermal disinfection, is achieved when all RMD surfaces have been exposed to hot water at a defined temperature for a minimum contact time.
Thermal disinfection is efficient to eliminate most microorganisms. Spores show higher resistance. Thermal disinfection can be characterized by the **A₀ concept**

Even after disinfection, an RMD may still carry some microorganisms and residual humidity and there are not protected by **packaging**. Precaution must be taken to limit environmental and handling contamination.
Maximum **storage** time after disinfection are usually defined by local guidelines or regulations.

Choice of cleaning & disinfection process

The **4 main categories** of cleaning and disinfection processes are

1. **Manual cleaning and disinfection**. RMD's are immersed and manually processed in cleaning and then disinfection baths, or in combined cleaning and disinfection solutions. When immersion is not allowed according to an RMD manufacturer's IFU, an RMD is wiped off.
2. **Automated washer disinfector** (for surgery and dentistry RMD's). Disinfection is thermal or chemical
3. **Ultrasonic cleaning**, when approved, according to an RMD manufacturer IFU,
4. **Automated Endoscope Reprocessors (AER)** for thermosensitive flexible endoscopes

The **Choice** of cleaning and disinfection process, cleaning, disinfection and lubrication agents go by the RMD manufacturer's IFU, and detergent as well as cleaning equipment manufacturers IFU's.

Automated endoscope reprocessor (AER)

Automated endoscope reprocessors are used for gastro-intestinal (GI) scopes (GI) and some other semi-critical single lumen flexible endoscopes. AER spray or flush pressurized water is mixed with a detergent and then spray or flush a disinfectant on surfaces and lumens of the endoscopes. All phases are **automatically** run, controlled and recorded.

Cleaning & disinfection and quality

Written cleaning and disinfection **standard operating procedures (SOP)** are prepared in accordance with **quality management** principles. Each step of the cleaning & disinfection process is an **improvement** to the former steps and does not impair the efficacy of the following stages.

For instance, final rinsing and drying are performed with adapted **water quality** and **air quality** to avoid recontamination of a disinfected RMD.

User supervises or performs **process validation** and, in particular, controls that:

- **Installation** of cleaning and disinfection workstation or equipment conforms to manufacturer recommendations
- **Instruction for use, maintenance manuals, and test and calibration certificates**, are available
- **Standard Operating Procedures (SOP's)** are up to date. SOP's are available for each RMD or group of RMD's requiring a similar cleaning and disinfection process. For a newly purchased **RMD**, a new SOP is defined if an existing one cannot be used. When possible SOP's provide quantitative and qualitative criteria for manual operations (e.g. brush until no soil is visible, the number of times a lumen should be swabbed etc..)
- **Systematic and periodic routine controls** are in place (see below)
- **Occupational health and safety** considerations (in particular exposure to liquid and vaporized chemicals, aerosols and injuries by potentially contaminated RMD's)
- Reprocessing fluids are discarded according to local **waste management** rules.
- **Training** (including training on occupational health and safety measures) is up to date, executed and training certificates are available.
- **Maintenance** plans are in place for washer-disinfector, ultrasonic cleaners and dosing pumps.
- **Traceability** is operational



WFHSS key recommendations for cleaning & disinfection

1. The **cleaning & disinfection** process complies to instructions for reprocessing of an RMD manufacturer. It is implemented according to manufacturer' IFU's for an RMD, detergent, disinfectant and reprocessing equipment.
2. **Thorough and consistent Cleaning** is essential for efficient disinfection and sterilization. Progress of minimally invasive surgery often means complex, narrow geometries, difficult to access and hidden to visual control. Inconsistent cleaning allows the progressive development of biofilms or mineral deposits.
3. Objective of disinfection depends on intended use of RMD
 - **When done in preparation for sterilization**, disinfection improves the preparation of RMD for sterilization. It may be required or recommended in some countries as an **occupational health and safety** measure.
 - When disinfection is the **last step before use of the RMD on a patient**, targeted efficacy is defined, with infection control, according to **Spaulding classification** principles. Disinfectant must comply to locally applicable **international standards**
4. **Automated cleaning and disinfection** in a WD or an AER is preferred to **manual**
 - Ultrasonic or manual precleaning may be needed for complex or heavily soiled RMD's. Ultrasonic reprocessing must be allowed by an RMD manufacturer's IFU.
 - Thermal WD are preferred for heat and moisture resistant RMD.
 - WD and AERs that comply with **international standards** ^{1,2,3,4,5,6,7} are preferred



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- **Systematic and periodic routine controls** are in place (see below)



- **Occupational health and safety** considerations (in particular exposure to liquid and vaporized chemicals, aerosols and injuries by potentially contaminated RMD's)
- Reprocessing fluids are discarded according to local **waste management** rules.
- **Training** (including training on occupational health and safety measures) is up to date, executed and training certificates are available.
- **Maintenance** plans are in place for washer-disinfector, ultrasonic cleaners and dosing pumps.
- **Traceability** is operational



WFHSS key recommendations for cleaning & disinfection

1. **The cleaning & disinfection** process complies to instructions for reprocessing of an RMD manufacturer. It is implemented according to manufacturer' IFU's for an RMD, detergent, disinfectant and reprocessing equipment.
2. **Thorough and consistent Cleaning** is essential for efficient disinfection and sterilization. Progress of minimally invasive surgery often means complex, narrow geometries, difficult to access and hidden to visual control. Inconsistent cleaning allows the progressive development of biofilms or mineral deposits.
3. Objective of disinfection depends on intended use of RMD
 - **When done in preparation for sterilization**, disinfection improves the preparation of RMD for sterilization. It may be required or recommended in some countries as an **occupational health and safety** measure.
 - When disinfection is the **last step before use of the RMD on a patient**, targeted efficacy is defined, with infection control, according to **Spaulding classification** principles. Disinfectant must comply to locally applicable **international standards**
4. **Automated cleaning and disinfection** in a WD or an AER is preferred to **manual**
 - Ultrasonic or manual precleaning may be needed for complex or heavily soiled RMD's. Ultrasonic reprocessing must be allowed by an RMD manufacturer's IFU.
 - Thermal WD are preferred for heat and moisture resistant RMD.
 - WD and AERs that comply with **international standards** ^{1,2,3,4,5,6,7} are preferred
 - Quality and performance of Dentistry washer-disinfector must be controlled
5. **Non automated cleaning and disinfection** is performed with care and consistency. When specified by RMD manufacturer's IFU, **ultrasonic cleaning** is efficient for devices with complex geometries. **Manual wiping** is used only when an RMD manufacturer's IFU does not allow immersion. **Combined manual cleaning and disinfection** with a cleaning&disinfecting formulation may be used on low risk items according to **Spaulding classification** principles or, if permitted by local regulation, **in preparation for sterilization**.
6. **Manual and automated cleaning and disinfection processes** are implemented according to **quality management** principles. **Standard operating procedures (SOP)** are up to date and describe systematic or periodic (visual controls of cleanliness and dryness are systematic). **Process validation** concerns both automated and manual processes. Operators **training** is regularly updated and controlled. Appropriate **occupational health and safety** measures and **traceability** are in place.

Cleaning & disinfection flowchart

Soiled RMD



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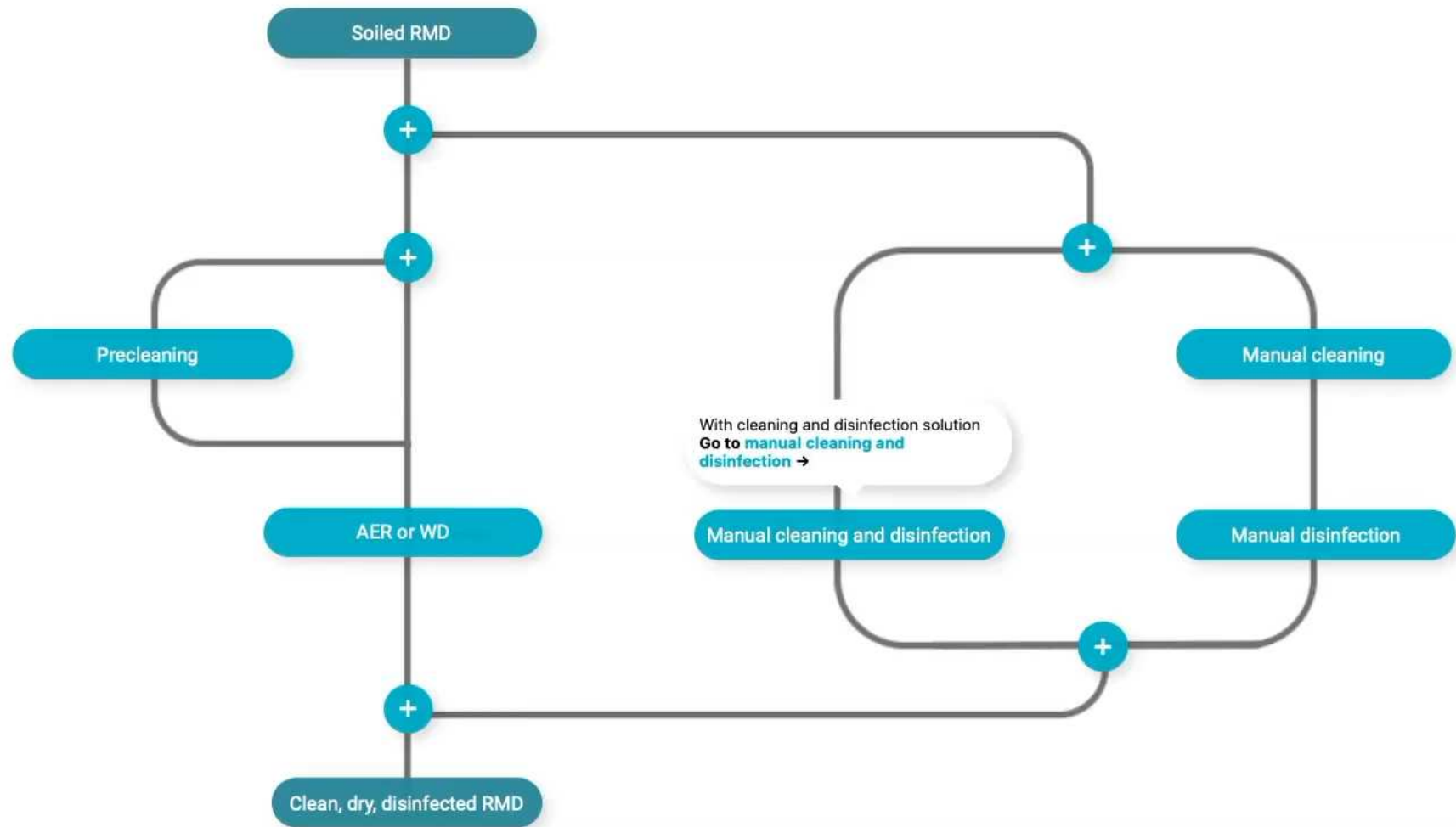
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Comments



Cleaning & disinfection flowchart



Cleaning & Disinfection

Objectives of cleaning and disinfection

Cleaning is intended to **remove matters** (e.g., patient secretion and inorganic material such as salts) from surfaces of **reusable medical devices** (RMD). **Disinfection**, is intended to **reduce the microbial load**

- Cleaning, disinfection or both take place in preparation for **sterilization**. Or with disinfection may be a final step before use of an RMD. Before **sterilization**, the primary objective is cleaning i.e. the withdrawal of matter that would interfere with a sterilizing agent and generate an RMD for sterilization and is required or recommended in some countries as an **occupational health and safety** measure for operators in
- As the **last step before use of and RMD**, the objective of cleaning and disinfection is to render the RMD safe for the patient according to **Sp**

Cleaning and disinfection takes place after the **point of use processing** and disassembly of multicomponent RMD

Although cleaning and disinfection are different in practice, they are often grouped in a cleaning and disinfection process (e.g., automated washer-disinfectors). This is the subject of chapter 4 of these guidelines

Principles of cleaning

Cleaning consists of **washing** followed by **rinsing**

- **Washing** is using water that contains a cleaning agent to remove soils from RMD surfaces.
- **Rinsing** clears the soils removed by washing as well as cleaning agent residues which would chemically interact with disinfection or sterilization

Main categories of detergent are : (1) neutral with or without enzymes, (2) mild alkaline with or without enzymes, (3) alkaline

Cleaning is performed according to the **manufacturers's IFU's (instructions for use) of an RMD, cleaning equipment and cleaning.**

Consistency of cleaning (i.e. regular application of a cleaning procedure after each use of an RMD) is key to avoid the progressive formation of biofilm

Principles of disinfection

Disinfection is **chemical** or **thermal**

Comments on WFHSS guidelines

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Hospital

Chapter select in the list

Cleaning & Disinfection

Your comment

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WFHSS Guidelines – Conclusion (1)

Improve practices

Framework for education & certification

Inspiration for national guidelines ?



WFHSS Guidelines – Conclusion (2)

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