Reprocessing Guidelines for Basic Neonatal Resuscitation Equipment in Resource-Limited Settings

Introduction Workshop

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Reprocessing for Basic Neonatal Resuscitation Equipment Workshop Agenda

8:00–8:15am	Registration
8:15–8:45am	Welcome and introductions
8:45–9:00am	Pre-test
9:00–10:00am	Reprocessing theory
10:00–10:15am	Tea break
10:15am–12:30pm	Hands-on reprocessing stations
12:30–1:30pm	Lunch
1:30 – 1:40pm	Post-test
1:40–3:45pm	Small group discussion
3:45–4:00pm	Tea break
4:00 – 4:45pm	Report on small group discussion
4:45 – 5:00pm	Workshop evaluation
5:00–5:15pm	Distribution of certificates of participation

Objective and aims of the workshop

OBJECTIVE: To introduce the new reprocessing guidelines for basic neonatal resuscitation equipment. The workshop will develop the expertise of the attendees and equip them with tools to implement changes both nationally and at facility level.

SPECIFIC AIMS

At the end of the workshop, participants will be able to:

- Describe the new reprocessing guidelines and be familiar with all reprocessing steps.
- Understand the rationale for each step.
- Understand strategies to improve reprocessing of neonatal resuscitation equipment both nationally and at the facility level.
- Be able to use and improve upon templates for training content, flow, and materials.

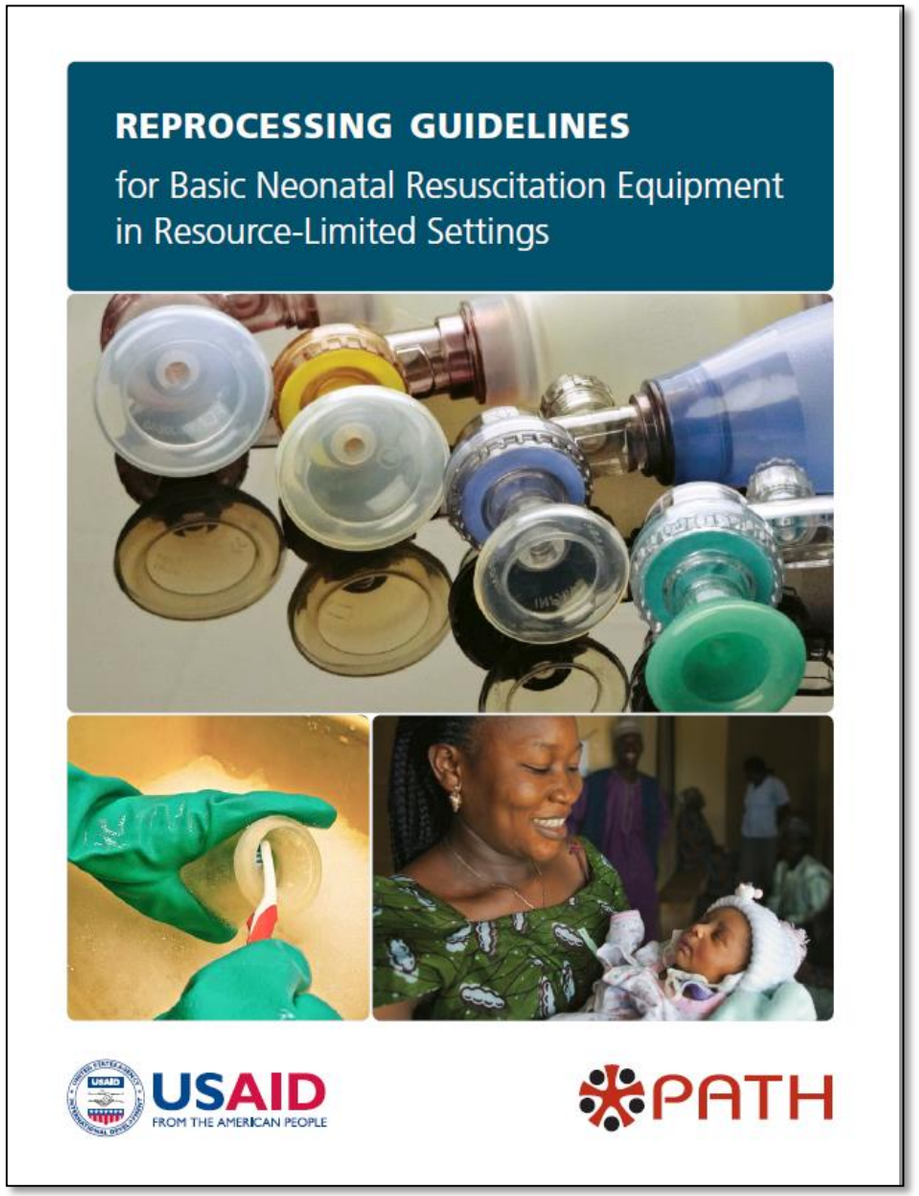
Introduction

- **Reprocessing**: multistep process to clean, sterilize/high-level disinfect (HLD), and store reusable medical equipment to make it safe for use on next patient.
- Any object in health facility can serve as vehicle for transmission of hospital-acquired infections.
- Although resuscitation equipment may look clean, it can still harbor microorganisms (including the inside of the ventilation bag).
- Gram-negative bacteria thrive on **insufficiently reprocessed** or **improperly stored** medical equipment and are known to cause outbreaks.
- **Adequate reprocessing of medical equipment is essential to helping newborns survive.**

Photo credit: PATH/Amy MacIver

Content of guidelines

- Focus on basic neonatal resuscitation equipment to support Helping Babies Breathe implementation.
- Overview of reprocessing materials and equipment.
- Space planning and workflow.
- Detailed, step-by-step reprocessing instructions for each piece of equipment.
- Training and supervision considerations.
- Considerations for health facility administrators and ministry of health (MOH) officials.



Process to generate guidelines

- Recommendations based on the best available evidence as of November 2015.
- When no literature existed, a consensus process was used.
- Factors identified during a reprocessing assessment conducted by PATH were considered while developing recommendations.
- Guidelines underwent both internal and external review.

Members:

Process Leaders:

- **Manjari Quintanar Solares**, MD, MPH, PATH
- **Siobhan Brown**, MPH, CPH, PATH

- **Sherri Bucher**, PhD, MA, Indiana University School of Medicine
- **Annie Clark**, CNM, MPH, University Research Co., LLC
- **Pegeen Eslami**, MD, University of Massachusetts School of Medicine
- **Jennifer Gilbertson**, MSE, Laerdal Global Health
- **William Keenan**, MD, St. Louis University School of Medicine
- **Frode Liland**, MSc, MBA, Laerdal Global Health
- **Goldy Mazia**, MD, MPH, Maternal and Child Survival Program (MCSP)/PATH
- **Indira Narayanan**, MD, Independent Neonatology Consultant; Adjunct Professor, Georgetown University Medical Center
- **Susan Niermeyer**, MD, MPH, Helping Babies Breathe Editorial Committee/American Academy of Pediatrics; University of Colorado School of Medicine
- **Magdalena Serpa**, MD, MPH, MCSP/PATH
- **Michael Visick**, MD, MPH, Helping Babies Breathe Editorial Committee/American Academy of Pediatrics; Latter Day Saints Charities

Spaulding Classification System

Critical Items: Objects that enter sterile tissue or the vascular system and pose a high risk for infection if they are contaminated with any microorganism. Includes: surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities, etc.

Semi-Critical Items: Objects that come into contact with **mucous membranes or nonintact skin**. Must be **free from all microorganisms, but a small numbers of bacterial spores are permissible**. Includes: respiratory therapy (including **resuscitation equipment**) and anesthesia equipment, some endoscopes, esophageal manometry probes, cystoscopes, and diaphragm fitting rings, etc.

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Non-Critical Items: Objects that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms. Includes: bedpans, blood pressure cuffs, crutches, bed rails, floors, and patient furniture, etc.

Levels of disinfection for medical equipment

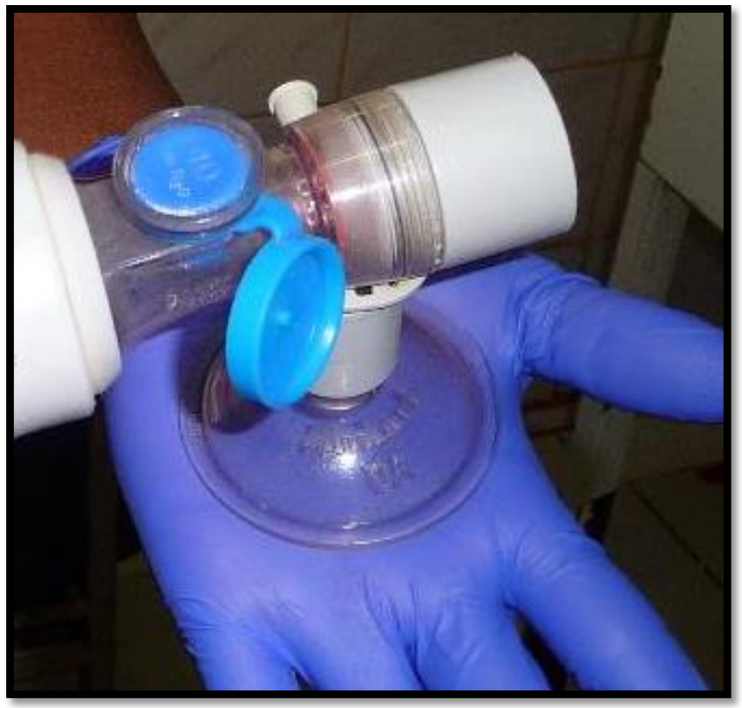
Disinfection level	Spaulding Classification	Microorganisms killed
Low	Non-critical (depends on equipment purpose)	Vegetative bacteria (except *M. tuberculosis)*, some fungi, and some viruses.
Intermediate	Non-critical (depends on equipment purpose)	*M. tuberculosis,* vegetative bacteria, most viruses, and most fungi, but does not always kill bacterial spores.
High	Semi-critical	All microorganisms except some bacterial spores, particularly if there is heavy contamination. HLD is the MINIMUM required for semi-critical items. Sterilization also appropriate for some semi-critical items.

National Infection Prevention and Control Guidelines

Reprocessing assessment

Conducted in Uganda in 2015 in urban and rural facilities.

- Nine facilities: Health Center III, Health Center IV, district hospital, regional hospital, national referral hospital.
- Thirteen units: labor wards and special newborn care units.
- Sixteen participants: nurses, midwives, nurse/midwives, student nurse. Included supervisory roles. Experience ranged



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Equipment: Single-use vs. reusable

Single-use equipment is not designed to be disassembled or withstand disinfection. It should be discarded after one use. Reuse of single-use equipment poses an infection risk to infants. One way to identify single-use equipment is to look for text imprinted into the equipment such as "single-use" or ⊗ .

Photo credit: PATH/Manjari Quintanar

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Reusable resuscitators may state "autoclavable," "reusable," or "silicone."

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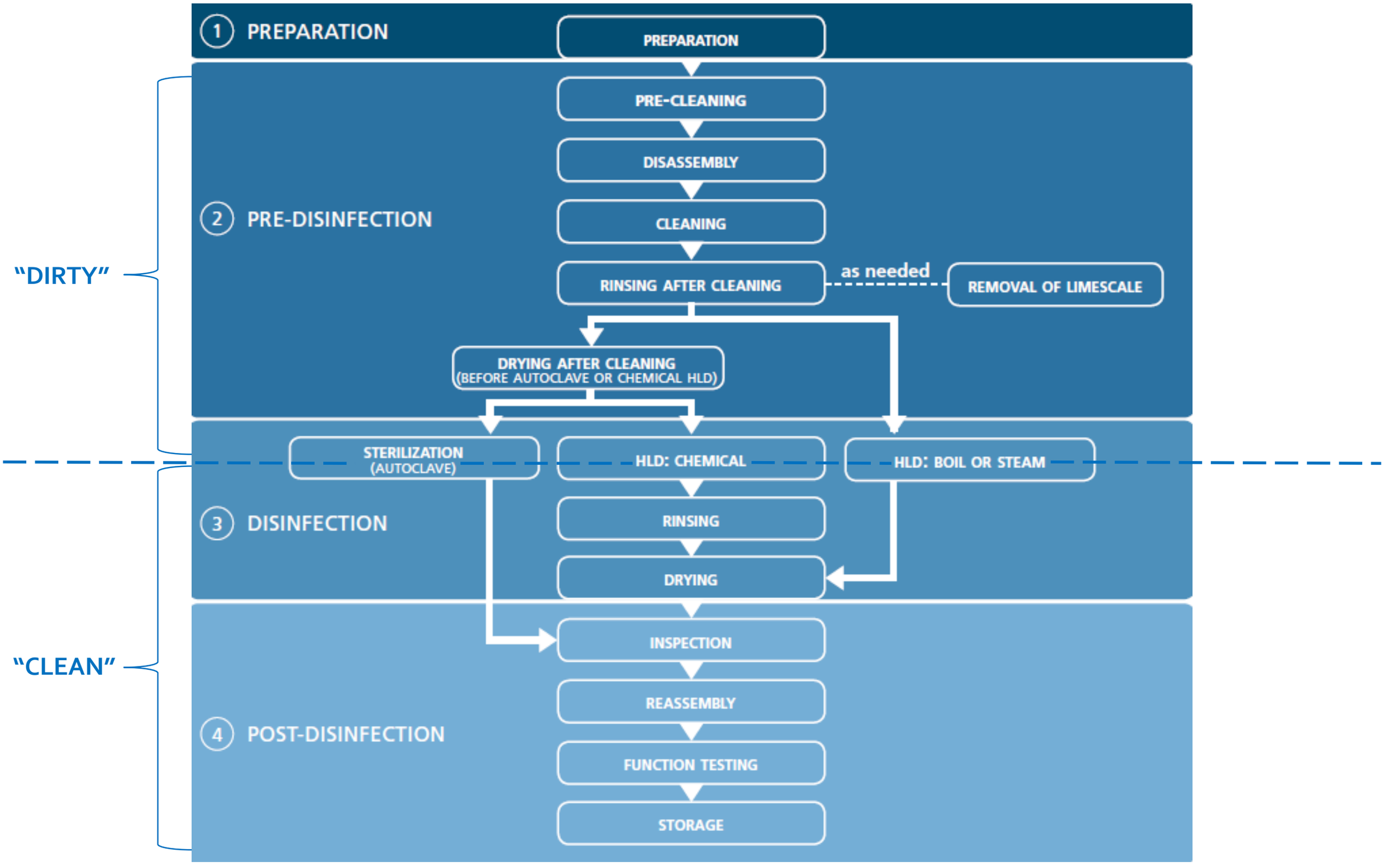
Outline of reprocessing stages and steps



Stage 1: Preparation

1. Preparation

Follow detailed instructions in the *Reprocessing Guidelines for Basic Neonatal Resuscitation Equipment in Resource-Limited Settings* (http://www.path.org/publications/details.php?i=2601).

- Wear complete personal protective equipment (gloves, cap, mask, eye protection, apron, boots)
- Clean the reprocessing area
- Prepare the reprocessing materials
- Label containers for reprocessing with name, date, and time of solution prepared

Rationale:

- Preparation in advance helps prevent transmission of microorganisms from the patient care area into the reprocessing area.
- Equipment should be reprocessed as soon as it is no longer needed at the bedside: if bodily fluids are allowed to dry on the equipment, they are more difficult to remove and interfere with effective sterilization/HLD.
- Dry organic matter leads to unnecessary discoloration and equipment damage.

Personal protective equipment

- Gloves (two types)
- Cap
- Mask
- Apron
- Eye protection
- Footwear

Utility or exam gloves

and

Sterile or HLD gloves

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Gloves

Use the same clean exam or utility gloves during the "DIRTY" steps.

Start with clean exam or utility gloves, then follow these steps:

PRE-CLEANING
Wipe the equipment.

→

DISASSEMBLY
Disassemble the equipment.

→

CLEANING and **RINSING**
Wash gloved hands in clean, soapy water and then begin cleaning equipment.
Rinse gloved hands and then begin rinsing equipment.

→

DRYING
Wipe dry equipment.

→

STERILIZATION or **HLD**
Prepare equipment for sterilization or HLD.

Use the same new sterilized or HLD gloves during "CLEAN" steps.

Start with sterile or HLD gloves, then follow these steps:

STERILIZATION or **HLD**
Remove equipment from HLD or sterilization.*

→

RINSING
(after chemical HLD)
Rinse equipment.
Be sure to completely rinse gloves well.

→

DRYING
(after HLD)
Wipe dry or arrange equipment for air drying.**

→

INSPECTION and **REASSEMBLY**
Inspect and reassemble the equipment.

→

FUNCTION TESTING and **STORAGE**
Function test the equipment and place it into storage.

* Remove the equipment from container/machine using sterile or HLD gloves or HLD forceps (instead of gloves). However, sterilized or HLD gloves must be worn to handle equipment during the next step.

** If air drying equipment, a new pair of sterile or HLD gloves will be needed when returning to complete the next reprocessing steps (Inspection through Storage) because the gloves used before will be contaminated by this time.

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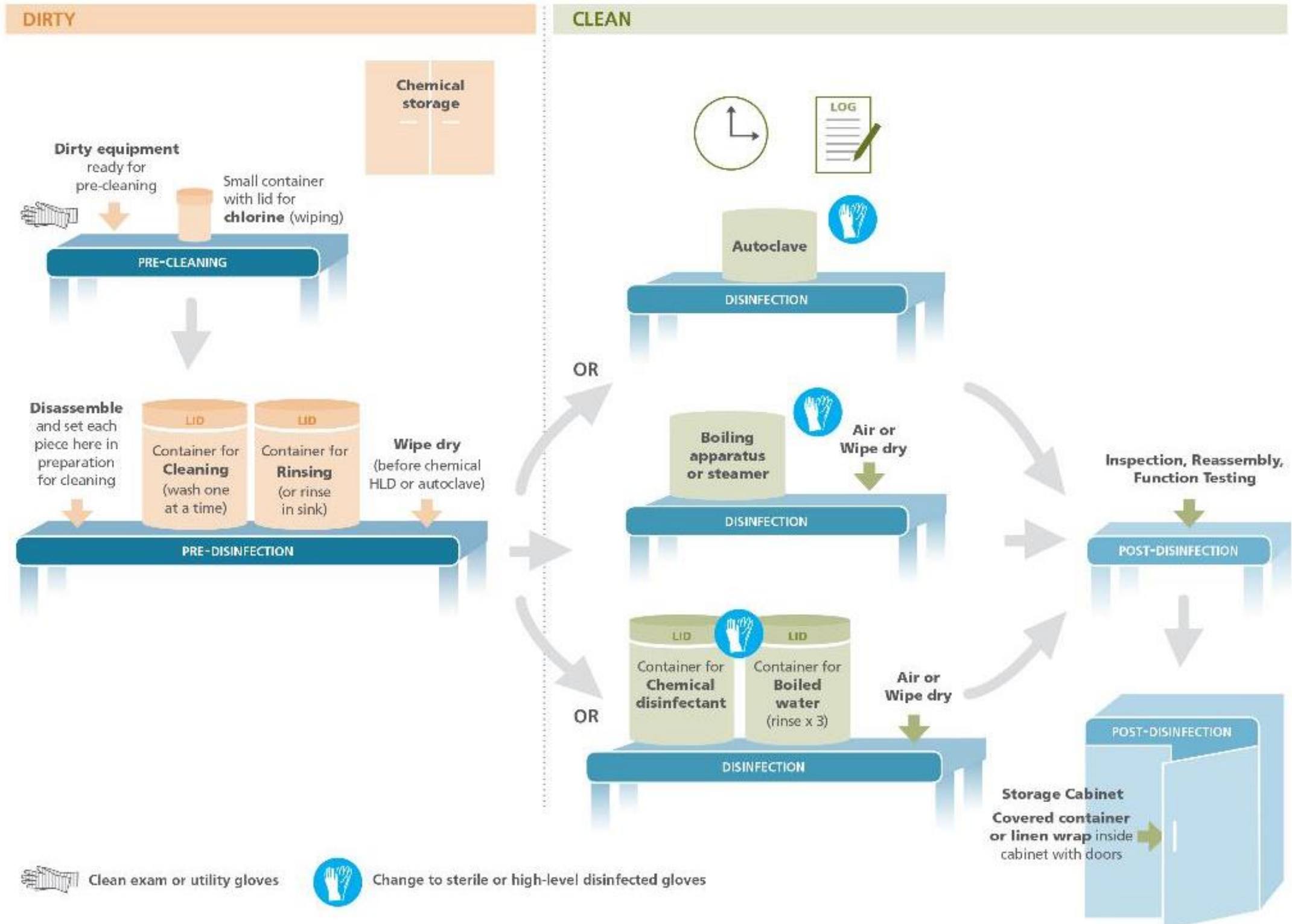
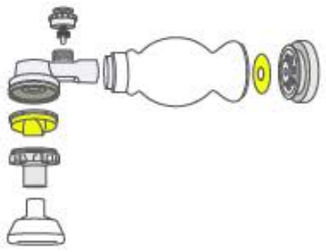
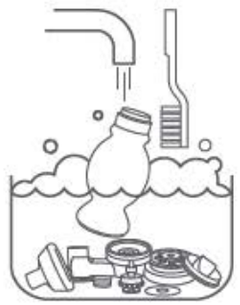
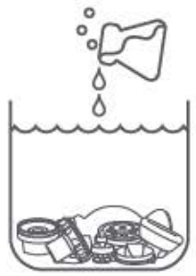
Reprocessing space layout



Stage 2: Pre-disinfection

2. Pre-disinfection

Pre-clean	Disassemble	Clean	Rinse	Remove lime scale (only if needed)	Dry (before sterilization or chemical disinfection)
					
Wipe equipment with clean gauze soaked in chlorine solution 0.5%.	Disassemble equipment completely.	Wash all parts with clean water and mild soap. Use a brush to remove any debris.	Rinse all parts in clean water.	Soak equipment in equal parts of water and white vinegar (3-5%) for 10 minutes then rinse. Repeat if necessary.	Wipe dry with clean gauze or cloth.

Rationale:

IMMEDIATE PRE-CLEANING: Protects health worker while handling equipment.
DISASSEMBLY: Exposes all equipment surfaces to the cleaning and sterilization or disinfection method.

CLEANING: Completely removes debris from the equipment.

RINSING AFTER CLEANING: Prevents soap residue from sticking to the equipment.

REMOVAL OF LIMESCALE: Only as needed, helps keep equipment in working order.

DRYING AFTER CLEANING: Avoids diluting chemical disinfectant or impacting level of drying during autoclaving.

Stage 3: Disinfection

3. Disinfection

Disinfect by one of the methods

Sterilization: Autoclaving

Follow device manufacturer's instructions or time/temperature table in guidelines.

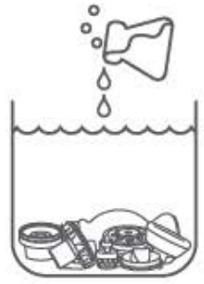
OR

High-Level Disinfection: Boiling or Steaming

Boil or steam with clean water for 20 minutes.

OR

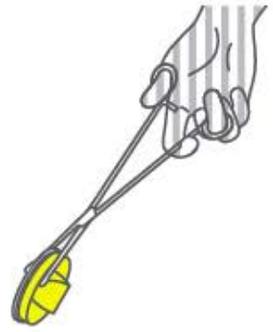
High-Level Disinfection: Chemical



Chlorine solution 0.5% - soak 20 min, or glutaraldehyde solution 2.4% - follow chemical manufacturer's instructions.

Rinse in 3 separate containers of boiled water for 1 minute each.

Remove



Remove parts using aseptic technique.

Dry

OR

Wipe dry with sterile gauze or air dry in a protected space.

Rationale:

STERILIZATION OR HLD: Eliminates all or most microorganisms from equipment surfaces.

RINSING AFTER CHEMICAL HLD: Removes all chemical residue from equipment after chemical HLD.

DRYING AFTER HLD: Avoids growth of new microorganisms and allows proper function testing.

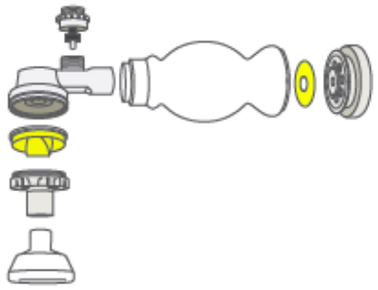
Stage 4: Post-disinfection

4. Post-disinfection

Inspect

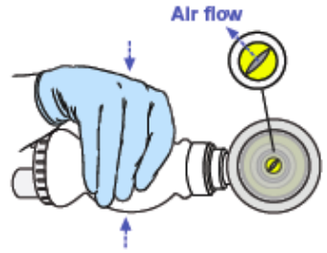
Visually inspect each part for damage, cleanliness, and mineral deposits. Repeat reprocessing if not clean. Remove damaged parts from service.

Reassemble

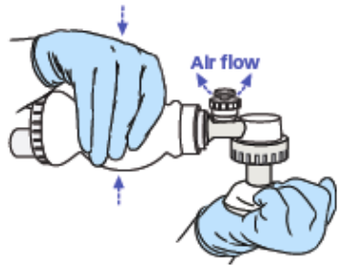


Reassemble equipment completely.

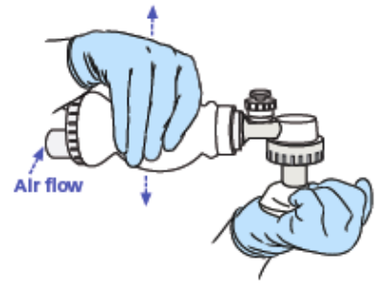
Test function*



Squeeze the bag and watch for the valve to open.



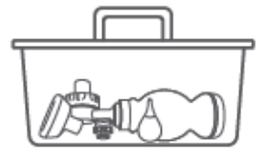
Seal the mask and squeeze hard enough to hear air escaping from the pressure release valve.



Maintain the seal and check that the bag reinflates after each squeeze.

Squeeze the suction device, block the tip, and release. The device should not expand until the tip is unblocked.

Store



Place equipment in a high-level disinfected plastic or metal container with tight-fitting lid or wrap in auto-claved linen.

*If any of the tests fail, disassemble and reassemble resuscitator, and repeat all tests. If a test still fails, remove the device from service.

Rationale:

INSPECTION: Ensures all equipment parts are intact.

REASSEMBLY: Ensures equipment is ready for use when resuscitation is required.

FUNCTION TESTING: Ensures equipment is in working order and has been properly reassembled.

STORAGE: Keeps equipment free of microorganisms and dust until it is needed.

Shaping the reprocessing plan

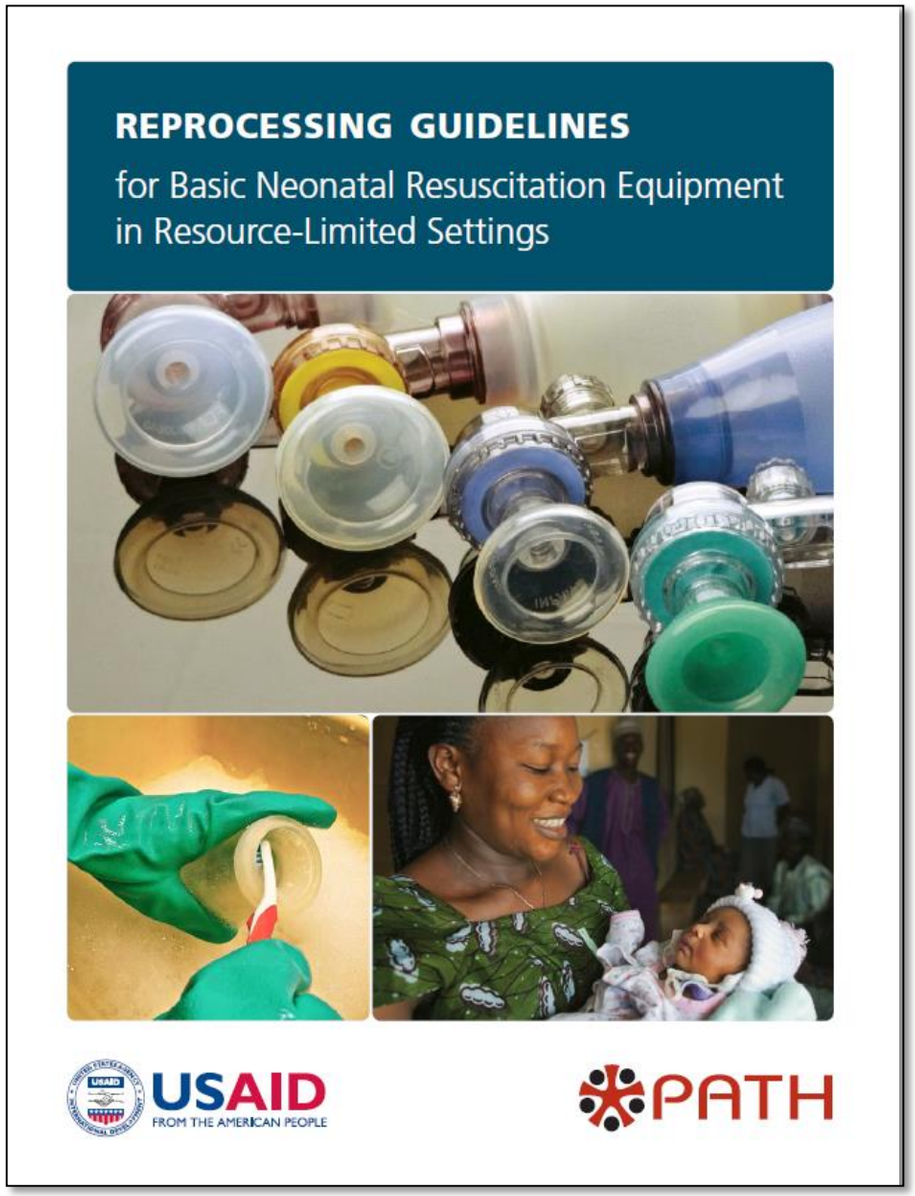
- Each facility should review this guide and existing national and/or facility policies and then choose their primary and secondary disinfection methods for the reprocessing of neonatal resuscitation equipment based on their unit/facility context.

- When developing a reprocessing plan, consider the following points:
  - Availability of reprocessing materials and resources.
  - Availability of medical equipment.
  - Training/educational resources needed for reprocessing.
  - Time needed for reprocessing.
  - Space needed for reprocessing.

Training and supervision

- Identify a reprocessing champion
- Establish the preferred workflow
- Apply consistent training for permanent and temporary staff
- Formalize reprocessing training plan:
  - Prior to joining unit
  - Yearly refresher
  - When changes in equipment or procedures occur
- Outline training content:
  - Infection risk
  - Rationale for each reprocessing step
  - Rationale for precise chemical dilution
  - Practice disassembly/reassembly of the ventilation bag and practice function testing
  - Device lifecycle and facility policy on malfunctioning equipment
  - Routine procedure for checking that enough resuscitation equipment is at hand
  - Specify the location of reprocessing guidelines within unit/facility
- Provide regular supervision

Getting acquainted with the manual



Other planning tools

It is necessary to have enough functional resuscitation equipment available in each unit that provides resuscitation to accommodate the number of patients that may need resuscitation. When planning, consider that equipment may be undergoing reprocessing and cannot be used for a period of time.

PATH has developed a variety of tools to aid in planning for the procurement of basic neonatal resuscitation equipment and its reprocessing:

- Quantification Tool for Basic Neonatal Resuscitation Commodities.
- A Toolkit for Procuring Quality-Assured Basic Neonatal Resuscitation Commodities.
- Reprocessing Guidelines for Basic Neonatal Resuscitation Equipment in Resource-Limited Settings (and associated job aids).
- Quality Improvement Road map.

These resources are available at www.path.org.

Acknowledgements

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Questions?