



Service Manual

BIOBUTTON® MULTI-PATIENT CLEANING AND DISINFECTION

INTRODUCTION

This document describes the detailed procedure for cleaning and disinfection of BioButton® Multi-Patient devices. Used BioButton Multi-Patient devices can be cleaned and disinfected for the purposes of reusability on a patient.

Warnings + Precautions

-  **Please follow the instructions and policies of your facility's infection control board or committee.**
-  Ultrasonic cleaning may interrupt or damage device components. Ultrasonic cleaners should not be used under any circumstances.

Facility Specifications

Prior to undertaking this cleaning and disinfection procedure, refer to your facility's procedures for BioButton device storage and charging.

Materials

PERSONAL PROTECTIVE EQUIPMENT (PPE)

ITEM	DETAILS / NOTES
Nitrile Gloves	Protects against contaminated surfaces and contact exposure.



Materials (Continued)

GENERAL EQUIPMENT

ITEM	DETAILS / NOTES
Timer	Used to measure the disinfectant wetting time.
Disinfectant Wipes	<p>Recommendation for an FDA-cleared product intended for low to intermediate level disinfection includes the following:</p> <ul style="list-style-type: none"> • CaviWipes™ Disinfecting Towelettes <ul style="list-style-type: none"> ◦ Active ingredient: Quaternary Ammonium, <20% Alcohol ◦ Kill time: 3 min ◦ After disinfection: Air dry • CaviWipes™ Bleach Disinfecting Towelettes <ul style="list-style-type: none"> ◦ Active ingredient: Sodium Hypochlorite ◦ Kill time: 3 min ◦ After disinfection: Air dry • Super Sani-Cloth® Germicidal Disposable Wipes <ul style="list-style-type: none"> ◦ Active ingredient: Isopropanol, Ammonium Chloride ◦ Kill time: 2 min ◦ After disinfection: Air dry • Sani-Cloth® Bleach Germicidal Disposable Wipes <ul style="list-style-type: none"> ◦ Active ingredient: Sodium Hypochlorite ◦ Kill time: 4 min ◦ After disinfection: Air dry • Clorox Healthcare® Bleach Germicidal Disinfectant Wipes <ul style="list-style-type: none"> ◦ Active ingredient: Sodium Hypochlorite ◦ Kill time: 3 min ◦ After disinfection: Air dry

Procedure

PREPARATION

STEP	DETAILS / NOTES
1	Equip any appropriate PPE and procure the disinfectant wipes.
2	Ensure the area chosen for disinfection is free from any debris or other materials.
3	Using the disinfectant wipes, wipe down the surfaces that will be used for cleaning and disinfection.



Procedure (Continued)

CLEANING

STEP	DETAILS / NOTES
1	Use a disposable disinfectant wipe to wipe all device surfaces until visibly clean. Note: When wiping, pay extra attention to device seams and crevices.
2	Visually inspect the BioButton device to ensure all adhesive residue or other debris has been removed.
3	Inspect the BioButton device for any signs of physical damage, such as cracks, punctures, swelling, bulging, deformation of the enclosure, or separation of the casing. If you notice any damage or signs of a potential battery issue, stop using the device immediately and do not attempt to charge or repair it. Contact BioIntelliSense to return the device if further evaluation is needed. If return is not feasible, dispose of the BioButton in accordance with your local regulations for lithium-ion batteries.

DISINFECTION

STEP	DETAILS / NOTES
1	Procure the disinfectant wipes.
2	Use the disinfectant wipe to wipe down all BioButton device surfaces until visibly clean. Note: When wiping, pay extra attention to device seams and crevices.
3	Visually inspect the BioButton device to ensure all adhesive residue or other debris has been removed. If they have not, use an additional disposable disinfectant wipe, repeat step 2.
4	Use the timer to ensure the BioButton device stays damp with the disinfection solution for the indicated wet time in the materials table above (2 to 4 minutes depending on wipe). If the device dries prior to the wet time, use a new disinfectant wipe and wipe the BioButton device again.
5	Once complete, the BioButton device has been disinfected and is ready for re-use. Remove the devices and accessories from the cleaning and disinfection area.



Device Disposal

Dispose of the BioButton device if:

- BioButton device cannot be cleaned properly or there is uncleanable residue present
- There is visible discoloration, material degradation, or physical damage to the BioButton device
- BioButton device is unable to activate or connect per the device's instructions for use

Refer to local e-waste disposal regulations to properly dispose of the BioButton device.

Terms + Definitions

TERM	DEFINITION
AAMI	Association for the Advancement of Medical Instrumentation.
Cleaning	<p>Per the FDA: Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use. Also, the removal, usually with detergent and water, of adherent visible soil, blood, protein substances, and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.</p> <p>Per the CDC: Removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.</p>
CDC	Centers for Disease Control and Prevention
Decontamination	Per the FDA: Disinfection or sterilization of infected articles to make them suitable for use.
Disinfectant	<p>Per the FDA: An agent that destroys pathogenic and other kinds of microorganisms by chemical or physical means. A disinfectant destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores.</p> <p>Per the CDC: Usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects. EPA groups disinfectants by product label claims of limited, general, or hospital disinfection.</p>



Terms + Definitions (Continued)

TERM	DEFINITION
Disinfection	<p>Per the FDA: A process that destroys pathogens and other microorganisms by physical or chemical means. Disinfection processes do not ensure the same margin of safety associated with sterilization processes. The lethality of the disinfection process may vary, depending on the nature of the disinfectant, which leads to the following subcategories:</p> <ul style="list-style-type: none">• High Level Disinfection: A lethal process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.• Intermediate Level Disinfection: A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores.• Low Level Disinfection: A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.
FDA	Food and Drug Administration.
Original Device	A new, unused device.
PPE	Personal Protective Equipment.

Disclaimers

BioIntelliSense wearable sensor device type is categorized by FDA as “non-critical devices” (<https://www.fda.gov/media/80265/download>) whose surfaces contact only intact skin and do not penetrate it. According to the FDA guidance document, only low-level disinfection and intermediate-level disinfection are required – high-level disinfection is NOT required for this device type and use scenario. Cleaning is performed in compliance with the following standards:

- Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices (AAMI ST98:2022)
- Designing, Testing, And Labeling Medical Devices Intended For Processing By Health Care Facilities: A Guide For Device Manufacturers (AAMI TIR12:2000)

Contact Us

For non-urgent support or questions about our product, please call **888.908.8804 (US)** or email support@biointellisense.com

For more information, visit biointellisense.com/support



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