Cleaning and Disinfecting/Sterilizing
The Mark V+ Hearing Aid Suction Pump
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Mark V+ Hearing Aid Suction Pump

The Mark V+ Hearing Aid Suction Pump (Mark V for short) is a suction pump designed to suction cerumen and other debris from hearing instrument and earmold devices and surfaces. It also has the capability to blow air out for additional cleaning capabilities and includes a drying chamber for removing moisture from hearing instruments.

As illustrated in Appendix A, the Mark V is primarily a suction pump encased in plastic. It is equipped with various components and disposable items including:

1. Two (2) 36" clear tubes (one for suction port, one for pressure port)
2. Filter wand assembly (attach to one of the clear tubes)
3. Lid for the hearing aid drying chamber
4. Reamer
5. Set of suction needles

Mark V+ Hearing Aid Suction Pump and Infection Control

According to the CDC, touch and splash surfaces need to be disinfected between patients. Per outlined CDC infection control guidelines referenced in Appendix B, the outer surface of the suction pump, including handle, vacuum chamber cover, and selection switches should be cleaned and then disinfected with an appropriate hospital grade disinfectant after use.

Remaining parts and components of the Mark V should be properly cleaned and either disinfected or sterilized, depending on the specific item. Items meeting the definition of a critical instrument should be either disposed of after use or cleaned and then properly sterilized prior to reuse. Other components that do not qualify as critical instruments can be properly disinfected prior to reuse.

Within the context of the Mark V, the only component potentially meeting the technical definition of a critical instrument is the suction needle. This part is inserted into various portions of the hearing aid during suctioning, making the most direct contact with contaminated cerumen and/or other material. Because the suction needle is not inserted into a human ear and used on hearing aids already removed from the ear canal, it could be categorized as a non-critical instrument within the context of Mark V use. The goal of this

document is to provide infection control recommendations and for each facility to work with their own infection control administrators to make the most informed decision.

Sterilization challenges inherent to VA approved sterilants:

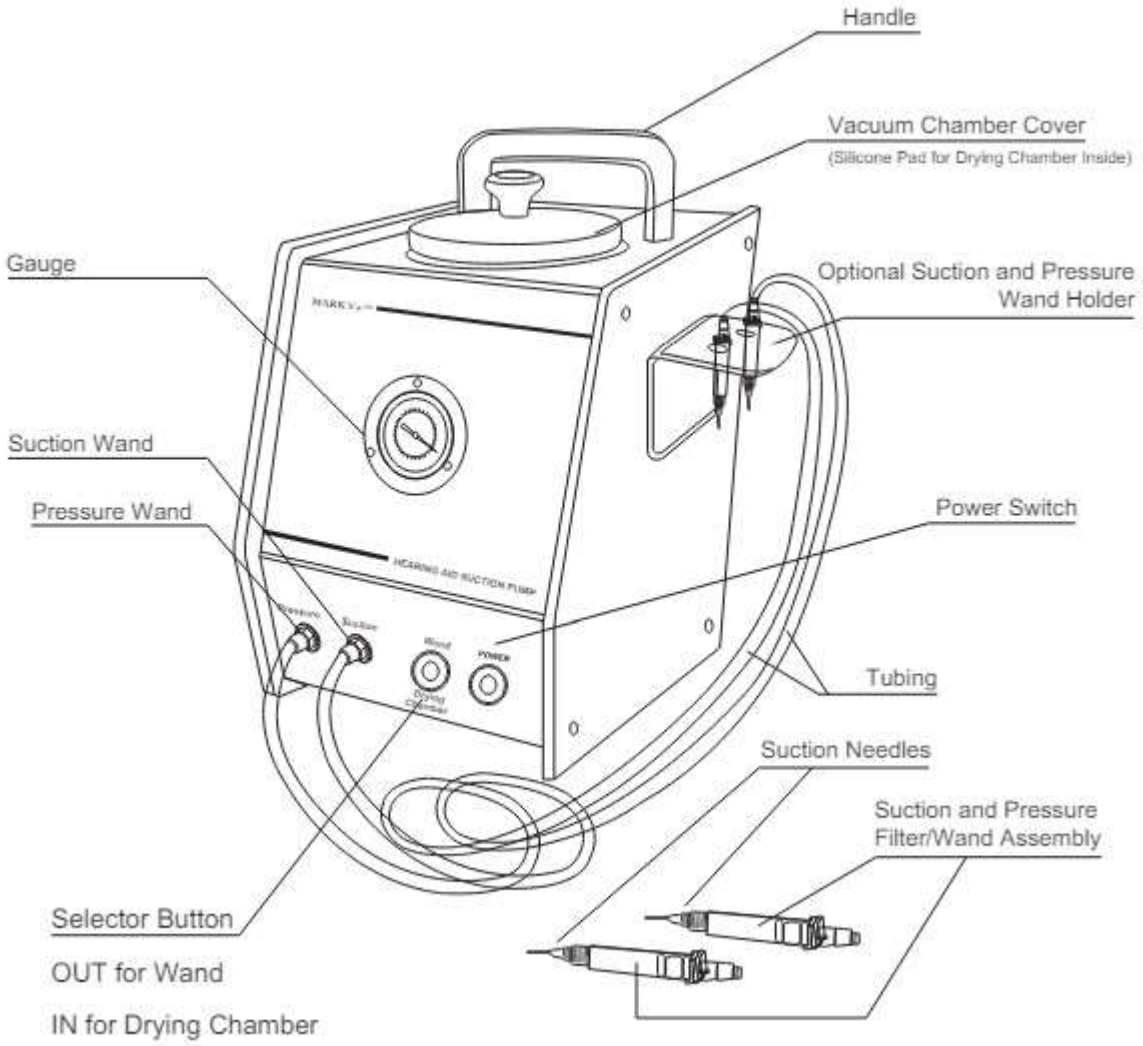
The use of heat pressurization via an autoclave may be used to sterilize steel suction tubes. In the event gas sterilization is an available, this option is considered suitable for steel suction tubes as well. Typically, this process involves the use of Ephylene Oxide although there may be other alternative gases used. In the absence of gas sterilization or access to an autoclave, the other option is to sterilize instruments via cold sterilization.

There are only two EPA-approved liquid chemicals that may be used for sterilization. Glutaraldehyde solutions in concentrations of 2% or higher (i.e., brand name products such as Wavicide, Cidex)or 7.5% or higher levels of hydrogen peroxide (H_20_2) (i.e., brand name products such as Sporox) are the only chemicals approved by the EPA for cold sterilization. It is the current understanding of Oaktree Products, Inc. that the V.A. system has not approved the use of glutaraldehyde-based sterilants, permitting the use of only those sterilants containing 7.5% or higher levels of H_20_2.

Sample Work Practice Controls for Mark V+ Suction Pump

- AFTER EACH USE ○ Following the use of Mark V, detach suction needle suction with appropriate personal protective equipment (e.g., glove, gauze pad, tissue) and dispose of in designated container
    - Using disinfectant towelette, wipe entire surface of the Mark V+ (including inside of drying chamber and drying chamber lid) and attached components to clean the unit.
    - Repeat the procedures with a fresh disinfectant towelette to disinfect the unit and attached components
- AT THE END OF THE DAY ○ Immediately following last use of the equipment for the day, repeat the after each use procedure
    - Detach clear tubes from the pump and remove filter wand assembly.
    - Wash inside and outside of clear tubes in the sink with soap and running water; remove and set aside to dry overnight
    - NOTE: replace clear tubes as needed

Appendix A: Infection Control Background Information



Appendix B: Infection Control Background Information

The information is taken from the copyrighted text "Infection Control in the Audiology Clinic" with permission from the publisher Auban, Inc. For more detailed information, contact Oaktree Products, Inc. at (636) 530-1664.

Infection control refers to the conscious management of the environment for purposes of minimizing or eliminating the potential spread of disease.[1,2] In response to the AIDS epidemic, during the mid to late 1980's, the Centers for Disease Control and Prevention (CDC) issued several recommendations and guidelines for minimizing cross-infection of bloodborne diseases to healthcare workers. These guidelines were based on the principle that every patient is assumed to be a potential carrier of and/or susceptible host for an infectious disease. Eventually, these pronouncements were officially formalized into the Universal Blood and Bloodborne Pathogen Precautions. More commonly referred to as universal precautions, the general pronouncements are as follows:

1. Appropriate personal barriers (gloves, masks, eye protection, gowns) must be worn when performing procedures that may expose personnel to infectious agents
2. Hands must be washed before and after every patient contact and after glove removal
3. Touch and splash surfaces must be pre-cleaned and disinfected
4. Critical instruments must be sterilized
5. Infectious waste must be disposed of appropriately

CDC 1987[3]

Differentiation of Terms:

Cleaning refers to procedures in which gross contamination is removed from surfaces or objects without killing germs.[1,2] It does not necessarily involve any level of germ killing but cleaning is an important prerequisite for other processes in which killing germs remains an objective. Cleaning must occur prior to disinfection or sterilization as the effectiveness of these procedures may be compromised without it.

Disinfection refers to a process in which germs are killed. The term encompasses a wide range of germ killing.[1,2] Levels of disinfection vary according to how many and what specific germs are killed. Household disinfectants kill a limited number of germs commonly found in the household. In contrast, hospital-grade disinfectants are much stronger and kill a larger number and variety of germs. As such, hospital-grade disinfectants should be incorporated in infection control protocols implemented in patient care settings, including clinics, hospitals, or private practice facilities where audiology services are provided.

Sterilization involves killing 100% of vegetative microorganisms, including associated endospores.[1,2] When microbes are challenged, they revert to the more resistant life form called a spore. Sterilants, by definition, must neutralize and destroy spores because if the spore is not killed, it may become vegetative again and cause disease. Whereas disinfection may kill some germs, sterilization, by definition, kills all germs and associated endospores each time.

Cleaning: removal of gross contamination
Disinfecting: killing a percentage of germs
Sterilization: killing 100% of germs including endospores

According to the CDC, critical instruments must be sterilized. Critical instruments refer to those instruments or objects introduced directly into the bloodstream (e.g., needles), noninvasive instruments that encounter intact mucous membranes or bodily substances (e.g., blood, saliva, mucous discharge, pus), or instruments that can potentially penetrate the skin from use or misuse. Non-critical items are those instruments or objects that either do not ordinarily touch the patient or touch only the externally intact skin.

References:

1. Bankaitis, A.U. and Kemp, R.J. (2003). *Infection Control in the Hearing Aid Clinic*. Boulder, CO: Auban.

2. Bankaitis, A.U. & Kemp, R. J. (2005). *Infection Control in the Audiology Clinic* (2nd edition). St. Louis, MO: Auban, Inc.
3. CDC. (1987). Recommendations for prevention of HIV transmission in healthcare settings. *MMWR*, 36(2s).