Example of a TempaChek™-DL Policy for temperature for monitoring of an automated instrument washer/disinfector process using theTempaChek™-DL

NOTE: This document is an example of a policy that may be instituted in a health-care facility for the TempaChek™-DL for temperature monitoring of an automated instrument washer/disinfector process using the TempaChek-™DL. The actual policy in a facility must be based on variables, logistics, and risk-assessments that are specific to your facility.

Subject: Temperature monitoring of the Automated Instrument Washer/Disinfector

Department: Central Service

Approved By: [Name of Dept Supervisor/Manager]

Effective: [Enter the date when this will take effect]

Revised: June 2021

Purpose: To monitor the temperature of automated instrument washer/disinfector process to ensure proper cleaning and reduce risk to personnel or patients.

Policy: To perform daily the testing of the various stages of the temperature within a medical automatic washer.

Rationale: Cleaning, not sterilization (or disinfection), is the first and most important step in any instrument processing protocol. Without first subjecting the instrument to a thorough, validated, and standardized (and ideally automated) cleaning process, the likelihood that any disinfection or sterilization process will be effective is significantly reduced.

- Washers fail to clean for many reasons. Temperature is one of the reasons. The TempaChek™-DL provides a means of monitoring the temperature at various stages within the automatic washer that influence the effectiveness of a washer.

- Proper cleaning is critical. The TempaChek™ -DL provides an independent objective test of the temperature and allows the Sterile Processing professional to monitor and ensure proper cleaning in the automated instrument washer/disinfector process concerning temperature.

- The TempaChek™-DL is the first device to bring data logging capabilities to the reprocessing equipment used by Central Sterile Processing Departments.

- This includes the cart washer, the ultrasonic and the automated instrument washer.

- With the later, it is now possible to verify thermal disinfection temperature and time, because the TempaChekDL™ can record temperature data as frequently as every second.

- The TempaChek™-DL is accurate to within 1degree Fahrenheit. It is made of stainless steel, just like most surgical instruments and its resistivity temperature sensor reacts nearly instantaneously to temperature changes.

- JCAHO and AAMI both recommend that Sterile Processing departments have process performance in place. Using the TempaChek™-DL test according to the manufacturer's guidelines helps ensure adherence to both JCAHO and AAMI standards and thus a properly functioning cleaning process when it involves temperature.

Procedure:

"The problem risk analysis should identify, define and quantify the risk and identify actions that can be taken to resolve or prevent the risk. The System should be monitored to ensure that the risk has been corrected or prevented." [9]

Daily Temperature Testing:

- Follow manufacture guidelines concerning the daily inspection of equipment (spray arms, screens…)

- Bring to the attention any concerns on the equipment that the inspection revealed to the proper person in the department to address.

- The TempaChek™-DL can be run with other cleaning verification test.

- Placing the TempaChek™-DL in the DecontaminationEquipment

- The TempaChek™-DL data logger is waterproof, but it is small, so in order to use in a washer, it is a good idea to contain it in a small, covered container. If the basket has a lid (top) make sure you secure the lid after you place the TempaChek™-DL into the basket. (Fig.1)

- Placement in the washer is an important consideration. It really depends on the objective of your testing. If you want to test the absolute capabilities of your washer, you might place the device out toward the very furthest point from the center of the spinner arms.

If you are using a small basket, you may need to place the small basket in a larger, uncovered basket (see Figure. 1). Load the rack, and run the washer on your normal

instrument cycle, running in an empty washer.

The TempaChek™-DL can also be used in other decontamination equipment, including the cart washer and the ultrasonic cleaning. Follow similar procedures as with testing the instrument washer.

Figure 1

TempaChekDL™ Data Logger

Suggested Temperature Range:

- Pre -wash Temperature should not exceed 110 °F.
- Enzymatic stage temperature should not excide 140 °F (check with your detergent manufacture for the optimum temperature range of your product)
- Detergent stage is usually at 150 ºF to 160 ºF check with your manufacture of your detergent for the optimum range for your product.
- Thermal Disinfections should be at 180 ºF for at least 1 minute.
- Caution should be used after the cycle because the TempaChek™-DL might be hot let cool for a few minutes
- After the cycle is finished follow directions on how to download data into your departmental computer. Since computers are different at each medical facility refer to your specific medical

  facility policy on downloading the data into your computer. Generic directions can be found on the web at this link http://www.healthmark.info/ProFormance/How-To-Use-TempDL.pdf
- Download data by securing the TempaChek™-DL data logger into the USB

Adapter Reader. (Figure. 2). The USB Adapter is hooked up to your hospital computer.

- Record results on log sheet.
- Report any deviation from targeted temperature.

Note: Each medical automatic washer has their own set of temperature ranges for each stage of cleaning; consult the manufactures for the optimum temperature range for your equipment.

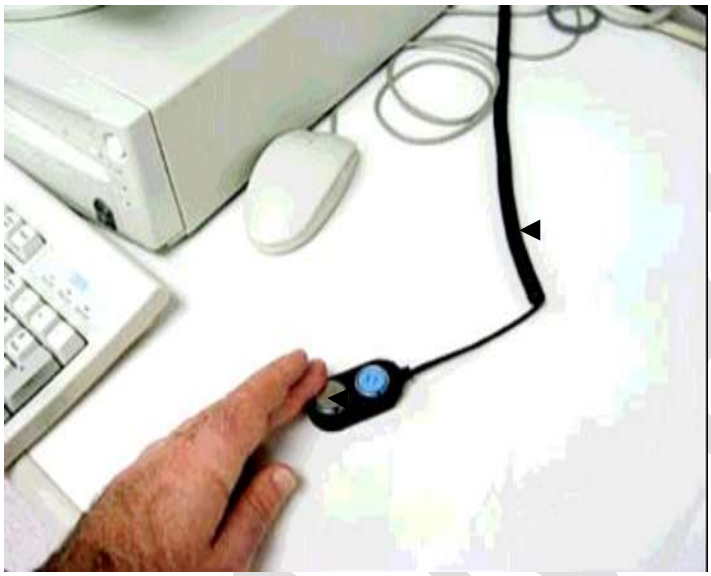

Figure 2

Maintenance on Equipment:

- After any maintenance on the equipment, perform temperature test using the TempaChek™-DL to ensure that the equipment is reaching the proper temperature at all stages.
- Have the maintenance person wait until the test results are complete before leaving.

Responsibility:

Central Service personnel are responsible for the proper use, result interpretation, and documentation of the TempaChek™-DL when used on an automated instrument washer.

Staff in-service and training on the equipment and proper use of the TempaChek™- DL should be done at least once each year.

References:

1. http://www.proformance-test.com/WallChart/WallChart.html
2. http://www.proformance-test.com/SupportMaterial/TechnicalBulletin1.html
3. http://www.proformance-test.com/SupportMaterial/BloodAsASoilonSurgicalInstruments.htm
4. http://www.proformance-test.com/SupportMaterial/StandardisedTestSoilBlood1.htm
5. http://www.proformance-test.com/index.html
6. 510(k) Summary and Overview; Safety, Efficacy and Microbiological Considerations,. The System 83 plus Washer -Disinfector; Custom Ultrasonic, Inc,1998, page 7.
7. ANSI /AAMI ST79:2017; Section 14.2.1 Quality process improvement, page 102.
8. JCAHO Guidelines 2005
9. ANSI/AAMI TIR 12-2005
10. Managing Infection Control; Role of Temperature in the Cleaning Process; Basile & Kovach; 2003
11. http://www.healthmark.info/ProFormance/How-To-Use-TempDL.pdf