

May 18, 2011

Dear Valued Customer,

Advanced Sterilization Products (ASP) occasionally receives questions from customers related to the reprocessing temperature of CIDEX® Solutions. All CIDEX® Solutions including CIDEX® OPA, CIDEXPLUS® 28 Day Solution and CIDEX® Activated Dialdehyde must be used in accordance with their respective Instructions for Use (IFU), and these IFUs indicate a minimum temperature requirement for high-level disinfection. Whether reprocessing devices manually in a basin or reprocessing using a legally marketed Automatic Endoscope Reprocessor, the temperature of the disinfectant solution must meet or exceed the minimum requirement listed in the solution's IFU.

ASP is aware that regulatory and accrediting organizations have increased their scrutiny of CIDEX® Solution temperatures, and often now request objective evidence that reprocessing temperatures meet requirements. In many cases, the ambient temperature of a reprocessing area is sufficient to ensure the minimum reprocessing temperature is maintained during disinfection. In some cases, however, a reprocessing area may not be sufficiently warm to ensure a basin of CIDEX® Solution is above the required temperature, and in this case the CIDEX® Solution should not be used until the temperature is sufficient. Customers must make certain that the solution is warmed to the appropriate temperature before the reprocessing begins, and should have reasonable confidence that the minimum temperature is maintained or exceeded throughout the soaking time.

While ensuring the disinfectant solution temperature meets the minimum requirements is essential, ASP does not endorse any particular system to warm CIDEX® Solutions should they not meet the temperature requirement. ASP strongly recommends that our customers develop and discuss their internal practices for heating disinfectant solutions in cooperation with their Industrial Hygiene, Facilities and risk management personnel. Should a warmer be used with CIDEX® Solutions, heat only to meet or to marginally exceed the minimum required temperature. **DO NOT OVERHEAT CIDEX® Solutions**, as overheating may increase vapors of the solution in the work environment. Solution temperature should be regularly monitored when heating CIDEX® Solutions.

Our customers may select from numerous heating systems on the market today that may be used to safely and gently warm CIDEX® Solutions for manual reprocessing. ASP has performed limited testing on several such commercially available heating systems and has provided the information below to serve as an example only. In this example, a UL certified heating mat, impervious to water, is used to gently heat a basin of CIDEX® Solution.



Pictured:

CIDEX® Solution Tray w/ Cozy Warming Pad & Rack

Part Number: CWP Contact: 312.226.2473

Note: Do not use a heating mat on a countertop or surface that is heat sensitive or the surface may discolor or change shape. **Temperatures below the mat may reach 65** °C.

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ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.
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When heating a basin of CIDEX® Solution, it is important to ensure that the temperature is stable so that the minimum temperature is reliably met while not overheating the solution. Temperature control may be attained by using a temperature controller.

A temperature controller may be used to measure the temperature of the CIDEX® Solution and to apply the appropriate amount of power to the heater to maintain a specified temperature. In this scenario, the controller is first plugged into an outlet near the heating mat, the heating mat is then connected to the output of the controller, and finally the controller's temperature probe is placed into the CIDIEX® Solution. The tray's lid may then be sealed over top of the cord, and the temperature may be adjusted to the value appropriate for manual reprocessing. It is highly recommended that the temperature of the CIDEX® Solution be measured with a calibrated thermometer prior to each disinfection cycle, and that this temperature value be logged with the result of the CIDEX® Solution Test Strip used to verify the Minimum Effective Concentration.



Pictured (Available from Amazon.com):

HC-810M: Finnex Digital Temperature Heater Controller

(ASIN: B002TMTA7G)

While ASP does not endorse Cozy Products or Finnex, we are providing this information as an example of a heating system that may be used to gently warm CIDEX® Solutions in a basin above their minimum temperatures. If you have any questions please call ASP Customer Care Center at 1-888-783-7723.

Sincerely,

Tracey Grenkoski

US Group Product Director, High-Level Disinfection