March 9, 2017

**Hemotherm® CE Dual Reservoir Cooler-Heater Communication**

On October 13, 2016, the FDA issued an updated Medical Device Safety Communication regarding *Mycobacterium chimaera* (*M. chimaera*) infections associated with heater-cooler devices. This updated safety communication provides new recommendations to help prevent the spread of infection related to the use of certain heater-cooler devices.

Gentherm would like to inform you that we have had independent testing performed at Virginia Polytechnic Institute and State University by Dr. Joseph O. Falkinham, III, Professor of Microbiology. Dr. Falkinham is an expert on Nontuberculous Mycobacteria (NTM) and is an authority on NTM associated with Heater-Coolers. Testing concluded that **no NTM, specifically *M. chimaera*, were aerosolized from the Hemotherm® CE Dual Reservoir Cooler-Heater** even when the device was inoculated with high counts of *M. chimaera*.

For more information on the FDA's Safety Communication please visit their website at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm.

For more information about the Hemotherm® CE please visit our website at www.gentherm.com, or call us at 1-800-989-7373.

Sincerely,

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