

**Acknowledgments**

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\*Alaska, Colorado, Georgia, Hawaii, Maryland, Maine, Minnesota, North Carolina, Nebraska, New Mexico, New York (excluding New York City), Oregon, Rhode Island, South Carolina, Utah, Vermont, and Washington.

†Confidence intervals are approximate because, when adjusting for the clustered survey design, the confidence intervals computed were close to but not equal to  $\pm 1.96 \times$  standard error.

‡Stressors during pregnancy were categorized as (1) emotional (a very sick family member had to go into the hospital or someone close to the respondent died), (2) financial (the respondent moved to a new address, her husband/partner lost his job, she lost her job, or she had a lot of bills she could not pay); (3) partner-related (the respondent separated or divorced from her husband/partner, she argued more than usual with her husband/partner, or her husband/partner said he did not want her to be pregnant); and (4) traumatic (the respondent was homeless, she was involved in a physical fight, she or her husband/partner went to jail, or someone close to her had a problem with drinking/drugs).

# Notice to Readers: Medical Equipment Malfunctions Associated With Inappropriate Use of Cleaning and Disinfecting Liquids—United States, 2007

MMWR. 2008;57:152

ON OCTOBER 31, 2007, THE FOOD AND Drug Administration (FDA), in collaboration with CDC, the Environmental Protection Agency, and the Occupational Safety and Health Administration, issued a public health notification alerting health-care providers and the public about medical device malfunctions caused by improper use of cleaning and disinfecting liquids.\* Inappropriate use of cleaning and disinfecting liquids on certain electronic medical equipment can cause equipment damage and malfunctions, which might have serious, even life-threatening consequences. Under the Safe Medical Device Act, health-care facilities are required to report to FDA any medical device malfunctions that cause or could cause death or serious injury. This notice provides recommendations to help prevent medical device malfunctions attributed to improper cleaning and disinfection.

Cleaning and disinfection are important practices to ensure that medical equipment surfaces do not serve as reservoirs for infectious pathogens. Cleaning is designed to remove infectious pathogens from inanimate objects, whereas disinfection is the process by which remaining pathogens are inactivated. Each of these two distinct processes usually involves the use of liquids (i.e., water and detergents for cleaning and chemical disinfectants for microbial inactivation). Because many types of equipment used in health-

care settings have mated surfaces, moving parts, gaps, joints, and unsealed housings, improper cleaning and disinfection can create opportunities for fluids to enter the internal surface of medical equipment, resulting in damage that can cause or contribute to equipment malfunctions.

Health-care facilities, public health officials, and device manufacturers can take several measures to help improve device cleaning and disinfection and to prevent equipment malfunctions in the future. Facility staff should review equipment currently in use to determine which pieces of equipment have manufacturer instructions for cleaning but not for disinfection. Equipment that cannot be disinfected should be used in a way that minimizes the risk for contamination, for example, by positioning it far from contaminated areas or by covering it with a barrier that can be easily cleaned or replaced. If this is not possible, the facility should contact the manufacturer to discuss options for safe and effective disinfection. If the equipment is fluid-tight, and both cleaning and disinfection instructions are provided by the equipment manufacturer, the recommended cleaning agents and chemical disinfectants should be used and the conditions for their use followed. Finally, personnel responsible for cleaning and disinfection must be given appropriate training.

Reports of medical equipment malfunctions that cause or could cause death or serious injury should be made by using FDA's MedWatch 3500A form, available at <https://www.fda.gov/medwatch/getforms.htm>. Health-care facilities also are encouraged to report medical devices malfunctions that do not meet the mandatory reporting to MedWatch by telephone (1-800-332-1088); by fax (1-800-332-0178); by mail (MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787); or online (<https://www.fda.gov/medwatch/report.htm>).

\*Available at <http://www.fda.gov/cdrh/safety/103107-cleaners.html>.