

# YEAR 2000 UPDATE



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## MEDICAL DEVICES

### Overview

The possibility that medical devices will fail as a result of the year 2000 computer problem is a serious one. Most industries are facing Y2K-related problems, but nowhere is that problem more public than in health care and the medical devices upon which the industry is dependent. While others' problems are indeed formidable, rarely are they life-threatening.

Embedded chips make the use of these devices possible, and it is not clear how many of those chips will fail due to date-related glitches or what might be the impact of those failures. The health care industry is already facing a plethora of issues such as the potential regulation of HMOs, fraud and abuse enforcement, industry consolidation, the conversion of non-profit hospitals to for-profit status, and the privacy of medical records. Facing these questions, many health care providers and health care-related industries have not had the time or resources to address Y2K or the compliance of their product providers. Compounding the problem is the inconsistent information that they have received from some device manufacturers.

As the year 2000 approaches, agencies are clarifying the responsibilities of device manufacturers, and alerting them to their responsibilities to maintain quality controls. Such actions

have not come in the form of new regulations or legislation, but notices directed toward manufacturers regarding their ongoing obligations. The FDA and Department of Health and Human Services have attempted to prod device manufacturers into compliance with mixed results. Most of the calls for reporting have been voluntary, which has resulted in a slow response rate. The FDA's announcements have imposed no new requirements on manufacturers and importers, but serve to put them on notice that date processing problems will be regulated as are other malfunctions. To date, no new legislation has been passed to require that date-related processing problems are specifically addressed by manufacturers or importers.

In addition to adverse affects on the functioning of some devices, the FDA has also raised the issue of Y2K consequences on the design, production, and quality control processes of all FDA-regulated medical products—drugs and biologics, as well as devices. Manufacturing difficulties have the potential to seriously disrupt the availability of vital health care components.

### Embedded Chips

Microprocessors inside electronic devices, or "embedded chips," are an integral part of each device, facilitating everything from microwave ovens to escalators. It is not clear whether those chips will fail due to date-related malfunctions. Chip failure could manifest itself in several ways:

- The worst-case scenarios revolve around a vital device ceasing to function due to these errors.
- It is also possible that such a device would spew out bad data as a result of date-related processing errors. A monitor tracking progress over time would probably place 01/01/00 before 12/31/99 in chronological order. In this example, although the printouts might be incorrect, there might not be direct negative effects on patient care.
- The least severe failures would have no impact on basic functions and might even go unnoticed. For example, a chip not knowing the correct day of the week would probably show no visible errors in a medical device, but would be serious for street lights or building security systems, which are dependent on such information.

The Gartner Group has estimated that about two-tenths of one percent of embedded chips will fail as a result of the Y2K problem. Recent reporting has added reasons for optimism; even in those chips that have experienced date-related processing errors, the basic functions of the machines were not effected. The problem is finding the small number of chips (and the devices they operate) that do not work and repairing or replacing them.

However, given the ubiquity of embedded chips, minute odds such as one in five hundred could still have disastrous and widespread consequences. Moreover, the resulting wrongful death, personal injury and malpractice suits could balloon into shareholder or regulatory agency suits, ultimately threatening accreditation and customer confidence. The issue is immense.

Fortunately, these are all hypothetical problems. The date-related failures that have occurred thus far have not affected the machines' functionality. On New Year's Eve, the FDA warned health care providers about the expected failure of two devices, a defibrillator and a patient monitor. Neither error prevented the devices from operating, though the defibrillator did spew out bad data. The patient monitor has had problems with new year date rollovers in the past. While hypotheses abound, no one knows what failures will occur.

## Federal Action

Lagging behind in their own efforts, the federal government has been ineffective in moving device manufacturers toward compliance. Government agencies have attempted to pressure medical suppliers to reveal their progress.

- The Food and Drug Administration and the Veteran's Health Administration have each sent letters to manufacturers asking for reports on suppliers' compliance.
- The VHA is concerned because it operates hospitals across the country; the issue is also under the jurisdiction of the FDA, whose Center for Devices and Radiological Health is responsible for regulating medical devices in the U.S.
  - The FDA's first notice relating to the issue was sent in a letter to manufacturers on June 25, 1997. It recommended:
    - » That manufacturers assure in future pre-market submissions to the agency that their devices are Y2K compliant;
    - » That presently and previously marketed devices should be tested for compliance, and corrected, if necessary; and
    - » That all computer-controlled manufacturing process will function after 1999.
  - The letter also asked that manufacturers take steps regarding any changes made to existing products. If the only change was Y2K compliance, manufacturers generally do not have to obtain FDA approval of those designs, provided that the changes do not affect safety and effectiveness.
- In September, Senator Christopher Dodd (D-CT) publicized the names of the companies that have not reported their progress with the FDA in a speech on the Senate floor.

For health care providers and users of medical devices, the FDA has created a Web site to publish the responses received from manufacturers. A January 21, 1998 letter from the Department of Health and Human Services requested this

information. Unfortunately, the response level has been low. Further, the FDA does not verify—nor does it claim to verify—the accuracy of a manufacturer’s Year 2000 disclosures. While there would undoubtedly be personal injury and wrongful death litigation if such failures occurred, it is extremely difficult for consumers to plan around this horrible scenario.

The FDA’s searchable Biomedical Equipment Y2K Status Web site can be found at [http://www.fda.gov/scripts/cdrh/year2000/y2k\\_search.cfm](http://www.fda.gov/scripts/cdrh/year2000/y2k_search.cfm).

## Other Regulatory Responsibilities

Last June, the FDA published “Guidance on FDA’s Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problem.” The guidance, available at 63 Federal Register 34433 (June 24, 1998), is also available on the FDA’s Web site.

- While noting that it began investigating the problem in 1996, the FDA acknowledged that only manufacturers have detailed information of design specifics required to verify Y2K compliance. The notice was not a list of new requirements, but a specific explanation of how Y2K issues apply to existing regulations.
- Under 21 CFR part 806, Medical Device Corrections and Removals, manufacturers who detect flaws in their products must report that they have taken corrective action. If date-related failures pose an unreasonable risk of substantial harm to the public health, the FDA is authorized under section 518 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h) to require those manufacturers to provide free fixes, or to give notice to their purchases and to recall the product. If the product failures do not present risks to health, manufacturers are not required to report corrective actions or recalls, but must maintain records of such actions.
- The Quality Systems Regulation (21 CFR part 820) places a continuing burden on manufacturers to ensure and document adherence to Current Good Manufacturing Practices (CGMPs). Manufacturers are responsible for investigating device malfunctions and preventing potential malfunctions, including Y2K-related problems.

- Voluntary corrections and recalls will not be considered recalls by the FDA, provided that remediation occurs before any device failures and that the errors are narrowly related to Y2K.
- Under the Medical Device Reporting Regulation (21 CFR part 803), medical device user facilities—such as hospitals—and manufacturers must report serious injuries or deaths that may be related to the use of a particular device.

Quality Systems Regulations (and Good Manufacturing Practices for drugs and devices) require that manufacturers of FDA-regulated health care products (drugs and biologics as well as devices) maintain control and detailed records of their manufacturing and quality control processes. The FDA has expressed concern that Year 2000 problems will disrupt the manufacture and distribution of these products. Errors in computer-controlled design, production, quality control, distribution and record keeping systems could restrict the availability of critical health care components, resulting in shortages that could adversely affect the health of patients who use these products. Production and quality control problems could also result in products with incorrect expiration dates or other defects that compromise their safety or effectiveness. In letters issued in late 1998 and early 1999, the FDA has advised manufacturers of medical devices, drugs and biologics that high priority should be given to ensuring that all computer systems involved in manufacturing and quality control systems are tested and validated before January 1, 2000.

## Industry Responses

For its part, the Health Industry Manufacturers Association, an industry trade group, points out that larger manufacturers—companies that, according to HIMA’s Web site provide nearly 90 percent of health technology in the United States—have responded to FDA requests. In responding to Senator Dodd’s speech, HIMA blamed large corporate structures for the slow response rate, while noting a sharp increase in responses during the two months prior to the speech. According to a HIMA press release, “one can see how it may initially be difficult to determine whether a corporate headquarters has responded for all of its division or whether each division or subsidiary has provided compliance information for itself.” In

November, a HIMA press release announced that all of its members had responded to the FDA, and that the group

continues to take the issue seriously.

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**SPECIAL RECOGNITION TO JOSHUA ROVNER, YEAR 2000 UPDATE EDITOR,  
FOR HIS RESEARCH AND WRITING CONTRIBUTIONS.**