

Center for Devices and Radiological Health Food and Drug Administration

Computer-Controlled Potentially High-Risk Medical Devices – List of Device Types

In order to more sharply focus our efforts related to the possible impact of the Y2K date problem on medical devices, FDA has developed a list of types of computer-controlled, potentially high-risk medical devices that have the potential for the most serious consequences for the patient should they fail because of date-related problems. Inclusion of a type of device on this list does not mean that all devices of this type have a date-related problem (are Y2K non-compliant) or, if they are Y2K non-compliant, that they necessarily pose a significant risk to patients. Rather, this list includes those types of devices that could pose a risk to patients if the date-related failure affects the function or operation of the device. FDA will use this list to identify those devices (and manufacturers) that would present the most serious risks to patients if they experienced a Y2K related failure. This will help the agency to focus attention on the devices that could present the highest levels of risk.

The list includes the types of computer-controlled devices whose failure to function as designed or expected could result in immediate and serious adverse health consequences. These potentially high-risk devices are those that are:

- 1) Used in the direct treatment of a patient where device failure could compromise the treatment or could injure the patient, or
- 2) Used in the monitoring of vital patient parameters and whose data are immediately necessary for effective treatment, or
- 3) Necessary to support or sustain life during treatment or patient care.

The list does not include diagnostic devices whose failure would not result in immediate harm to the patient, even though the diagnostic information they provide might be unavailable or incorrect. However, a few diagnostic devices have been included, if the results of calculations or other information processing by the device would not be readily apparent to the user, and a Y2K failure of the device could reasonably lead to serious adverse health consequences before being detected by the user.

This list of computer-controlled potentially high-risk devices will be used by FDA for several purposes and can also provide a guide to healthcare facilities regarding the types of devices that should receive priority in their assessment and remediation of medical devices.

FDA will identify all manufacturers of these types of devices. These manufacturers will be candidates for further oversight to provide increased assurance that product Y2K status has been carefully assessed and that any Y2K-related upgrade has been developed and tested in accordance with the quality system regulations. That oversight may include facility inspection or audit. FDA will also ascertain whether these manufacturers have made Y2K status information

List of potentially high-risk device types

available to users, and that, where appropriate, users have received notification regarding any necessary remedial action that may be necessary.

This list should not be considered a definitive list of all high-risk devices. It was developed by FDA staff based on their assessment of the types of devices that have the greatest potential for direct patient risk should they fail to correctly process date-related information. The list may change as FDA receives comments on the types of devices included in the list.

FDA solicits comments from healthcare facilities, manufacturers and others regarding the device types included or omitted from this list. Any person wishing to suggest additions to or deletions from this list should provide that information and the rationale for the suggestion. These suggestions should be sent to the following address and should be received by July 15, 1999.

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The list below contains the potentially high-risk device types. Where the generic device type has been classified by FDA, the list includes the section number [in Title 21 of the Code of Federal Regulations where the device type is described](#). For those devices cleared for market through the Premarket Approval application process or which have not yet been classified, no classification regulation number is given.

A link is also provided to the [Federal Y2K Biomedical Equipment Clearinghouse Search](#) mechanism to determine the compliance status of medical devices, as reported by the device manufacturers. As an additional aid, a link is provided to the [Manufacturer Registration Database](#), which contains names and addresses of manufacturers who have registered with the FDA.

CLASSIFIED DEVICES

(Classification regulation number followed by classification name)

862.1345 GLUCOSE TEST SYSTEM

862.2140 CENTRIFUGAL CHEMISTRY ANALYZER FOR CLINICAL USE

862.2150 CONTINUOUS FLOW SEQUENTIAL MULTIPLE CHEMISTRY ANALYZER FOR CLINICAL USE

862.2160 DISCRETE PHOTOMETRIC CHEMISTRY ANALYZER FOR CLINICAL USE

862.2170 MICRO CHEMISTRY ANALYZER FOR CLINICAL USE

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- 864.9145 PROCESSING SYSTEM FOR FROZEN BLOOD
- 864.9175 AUTOMATED BLOOD GROUPING AND ANTIBODY TEST SYSTEM
- 864.9205 BLOOD AND PLASMA WARMING DEVICE
- 864.9575 ENVIRONMENTAL CHAMBER FOR STORAGE OF PLATELET CONCENTRATE
- 864.9700 BLOOD STORAGE REFRIGERATOR AND BLOOD STORAGE FREEZER
- 868.1150 INDWELLING BLOOD CARBON DIOXIDE PARTIAL PRESSURE (PCO₂) ANALYZER
- 868.1200 INDWELLING BLOOD OXYGEN PARTIAL PRESSURE (P_{O₂}) ANALYZER
- 868.1730 OXYGEN-UPTAKE COMPUTER
- 868.2375 BREATHING FREQUENCY MONITOR
- 868.2450 LUNG WATER MONITOR
- 868.5160 GAS MACHINE FOR ANESTHESIA OR ANALGESIA
- 868.5330 BREATHING GAS MIXER
- 868.5400 ELECTROANESTHESIA APPARATUS
- 868.5440 PORTABLE OXYGEN GENERATOR
- 868.5470 HYPERBARIC CHAMBER
- 868.5610 MEMBRANE LUNG (FOR LONG TERM PULMONARY SUPPORT)
- 868.5830 AUTOTRANSFUSION APPARATUS
- 868.5880 ANESTHETIC VAPORIZER
- 868.5895 CONTINUOUS VENTILATOR
- 868.5925 POWERED EMERGENCY VENTILATOR
- 868.5935 EXTERNAL NEGATIVE PRESSURE VENTILATOR
- 868.5955 INTERMITTENT MANDATORY VENTILATION ATTACHMENT

List of potentially high-risk device types

870.1025 ARRHYTHMIA DETECTOR AND ALARM

870.1750 EXTERNAL PROGRAMMABLE PACEMAKER PULSE GENERATOR

870.3535 INTRA-AORTIC BALLOON AND CONTROL SYSTEM

870.3545 VENTRICULAR BYPASS (ASSIST) DEVICE

870.3600 EXTERNAL PACEMAKER PULSE GENERATOR

870.3610 IMPLANTABLE PACEMAKER PULSE-GENERATOR

870.3700 PACEMAKER PROGRAMMERS

870.4220 CARDIOPULMONARY BYPASS HEART-LUNG MACHINE CONSOLE

870.4320 CARDIOPULMONARY BYPASS PULSATILE FLOW GENERATOR

870.4330 CARDIOPULMONARY BYPASS ON-LINE BLOOD GAS MONITOR

870.4360 NONROLLER-TYPE CARDIOPULMONARY BYPASS BLOOD PUMP

870.4370 ROLLER TYPE CARDIOPULMONARY BYPASS BLOOD PUMP

870.4380 CARDIOPULMONARY BYPASS PUMP SPEED CONTROL

870.5225 EXTERNAL COUNTER-PULSATING DEVICE

870.5300 DC-DEFIBRILLATOR LOW ENERGY (INCLUDING PADDLES)

876.5270 IMPLANTED ELECTRICAL URINARY CONTINENCE DEVICE

876.5630 PERITONEAL DIALYSIS SYSTEM AND ACCESSORIES

876.5820 HEMODIALYSIS SYSTEMS AND ACCESSORIES

876.5860 HIGH PERMEABILITY HEMODIALYSIS SYSTEM

876.5870 SORBENT HEMOPERFUSION SYSTEM

876.5880 ISOLATED KIDNEY PERFUSION AND TRANSPORT SYSTEM AND ACCESSORIES

880.5130 INFANT RADIANT WARMER

880.5400 NEONATAL INCUBATOR

List of potentially high-risk device types

880.5410 NEONATAL TRANSPORT INCUBATOR

880.5725 INFUSION PUMP

882.5820 IMPLANTED CEREBELLAR STIMULATOR

882.5830 IMPLANTED DIAPHRAGMATIC/PHRENIC NERVE STIMULATOR

882.5840 IMPLANTED INTRACEREBRAL/SUBCORTICAL STIMULATOR FOR PAIN RELIEF

882.5850 IMPLANTED SPINAL CORD STIMULATOR FOR BLADDER EVACUATION

882.5860 IMPLANTED NEUROMUSCULAR STIMULATOR

882.5870 IMPLANTED PERIPHERAL NERVE STIMULATOR FOR PAIN RELIEF

882.5880 IMPLANTED SPINAL CORD STIMULATOR FOR PAIN RELIEF

884.1700 HYSTEROSCOPIC INSUFFLATOR

884.1730 LAPAROSCOPIC INSUFFLATOR

884.2660 FETAL ULTRASONIC MONITOR AND ACCESSORIES

** The following device classifications include radiation treatment planning systems which are accessories to these device types.*

892.5050* MEDICAL CHARGED-PARTICLE RADIATION THERAPY SYSTEM*

892.5300* MEDICAL NEUTRON RADIATION THERAPY SYSTEM*

892.5700* REMOTE CONTROLLED RADIONUCLIDE-APPLICATOR SYSTEM*

892.5750* RADIONUCLIDE RADIATION THERAPY SYSTEM*

892.5900* X-RAY RADIATION THERAPY SYSTEM*

** The device classifications specified above, flagged with an asterisk, include radiation treatment planning systems which are accessories to these device types.*

POST-MEDICAL DEVICE AMENDMENTS CLASS III DEVICES, AND DEVICES NOT YET CLASSIFIED

VENTILATOR, HIGH FREQUENCY

List of potentially high-risk device types

CARDIOCONVERTER, IMPLANTABLE

DEFIBRILLATOR, AUTOMATIC IMPLANTABLE CARDIOVERTER

DEFIBRILLATOR, IMPLANTABLE, DUAL-CHAMBER

PULSE-GENERATOR, DUAL CHAMBER, IMPLANTABLE

PULSE-GENERATOR, PROGRAM MODULE

PULSE-GENERATOR, SINGLE CHAMBER, SENSOR DRIVEN, IMPLANTABLE

PULSE-GENERATOR, SINGLE CHAMBER

SYSTEM, PACING, TEMPORARY, ACUTE, INTERNAL ATRIAL DEFIBRILLATION

AUTOMATED BLOOD CELL AND PLASMA SEPARATOR FOR THERAPEUTIC PURPOSES

LIPOPROTEIN, LOW DENSITY, REMOVAL

SEPARATOR FOR THERAPEUTIC PURPOSES, MEMBRANE AUTOMATED BLOOD CELL/PLASMA

PUMP, DRUG ADMINISTRATION, CLOSED LOOP

PUMP, INFUSION, IMPLANTED, PROGRAMMABLE

KIT, TEST, ALPHA-FETOPROTEIN FOR NEURAL TUBE DEFECTS

STIMULATOR, CORTICAL, IMPLANTED (FOR PAIN)

STIMULATOR, ELECTRICAL, IMPLANTED, FOR PARKINSONIAN TREMOR

STIMULATOR, SACRAL NERVE, IMPLANTED

STIMULATOR, SPINAL-CORD, TOTALLY IMPLANTED FOR PAIN RELIEF

STIMULATOR, SUBCORTICAL, IMPLANTED FOR EPILEPSY

DEVICE, THERMAL ABLATION, ENDOMETRIAL

INSTRUMENTS USED TO SCREEN THE BLOOD SUPPLY FOR BLOODBORNE PATHOGENS

List of potentially high-risk device types

SOFTWARE, BLOOD BANK, STAND ALONE PRODUCTS