

KidNet Roundtable

May 15, 2008

1:00-2:00PM EDT

Adverse Event of Fire with an Infant Oxygen Head Hood

- An infant resting in a bassinet, under an infant warmer, had an oxygen hood in place. The oxygen hood was placed over the infant's head and was attached to an oxygen air blender for administration of 100% oxygen. As staff approached the bassinet, they observed a flash of flames under the oxygen hood. Staff removed the hood and removed the oxygen from the wall, extinguishing the fire with a blanket.

Infant Oxygen Head Hoods

- **What is it?**
 - a clear plastic hood that fits over an infant's head
 - different designs and sizes, some with potential ports for monitoring gas content
- **What is it used for?**
 - to deliver a constant concentration of oxygen
 - as support in cases of
 - mild respiratory distress syndrome (RDS)
 - transient tachypnea of the newborn (TTN)
 - meconium aspiration
 - neonatal pneumonia

Infant Oxygen Head Hoods

- Can be placed on infants in cribs, radiant warmers or incubators
- May be used along with nasal cannula to increase inspired oxygen content
- Oxygen is warmed and humidified, which can lead to fogging and limits visibility

Oxygen Content within the Hood

- Inspired oxygen content within the hood depends on:
 - Flow of oxygen
 - If too low, less delivered oxygen is available to the infant due to infiltration of environmental gas (21% oxygen on room air)
 - Remember, higher gas flows help wash out exhaled carbon dioxide
 - Concentration of oxygen
 - Reliable delivery of concentrations of 60% or less
 - Possible to deliver higher concentrations with higher flows and tighter seals

Oxygen Delivery via Infant Head Hoods

- A blender system is considered the most reliable way to deliver fixed oxygen concentration
 - Make sure to use the appropriate sized hood
 - Too large, the infant can slip out of the hood and oxygen may be diluted by leaks
 - Too small, infant may develop pressure points around the neck

Oxygen Delivery via Infant Head Hoods

- Monitor delivered oxygen concentrations by continuous or intermittent sampling (at least every hour) and record them.
- Calibrate oxygen monitors and analyzers to room air and 100% oxygen level every 8 hours or by hospital/product protocol.

Infant Oxygen Hood Considerations

- **Advantages**

- Oxygen can be warmed and humidified without pressure
- Hoods can be used for infants of various sizes in different types of beds
- Good for short term use (a few days maximum)

Infant Oxygen Hood Considerations

- **Disadvantages**

- oxygen content of inspired gas may vary with hood position, amount of leakage and movement of the infant out from under the hood
- Noise levels may be high when liter flow is high
- Caregiver ability to visualize the infant's face maybe be obscured due to fogging or condensation
- Carbon dioxide buildup if flow is low and the hood is well sealed and risk of positive pressure creation if the hood is well sealed and the gas flow is high
- High levels of humidity and condensation increase the risk of infection when hoods are used for extended periods.

Troubleshooting Tips

- If an infant experiences a desaturation, apneic, or bradycardic episode, check for:
 - Is the oxygen delivery system in place and functioning properly?
 - Is the infant under the oxygen hood?
 - Are the appropriate oxygen concentrations and flow rates being delivered?
 - Is the infant positioned properly? Infants can be in either the prone or supine position as long as proper monitoring is undertaken. Prone positioning has been shown to improve oxygenation.

Additional Tips

- Given that oxygen is a drug, some form of continuous monitoring of the infant's oxygenation (e.g., arterial blood gases, pulse oximetry) is needed for optimal therapy.
- Humidify delivered oxygen as dry gases are irritating to the airways. Replace humidifiers and tubing per institutional/product protocol to prevent respiratory therapy equipment from being a source of infection.

References

- Gardner, Sandra & Gerald Merenstein.
Handbook of Neonatal Intensive Care.
St. Louis : Mosby, 2002.
- St. Clair, Nancy, Suzanne Touch and Jay Greenspan. "Supplemental Oxygen Delivery to the Nonventilated Neonate." Neonatal Network. Sep. 2001: 39-46.

Adverse Event of Fire Involving an Infant Incubator

- While preparing to transport an infant to the intensive care nursery, an odor was noted by the MD and smoke was noted to be coming from the front of the isolette.
- The infant was removed without harm. Biomed evaluation found the jack on the power chassis assembly had overheated and melted.
- Biomed replaced the subassembly to fix the unit and pro-actively replaced the same subassembly on a second unit.
- The reporter indicates the incident may be age related since the units were purchased in 1981 and 1991 respectively and are still in use.

Adverse Events involving Fire with Incubators and Warmers

- An infant radiant warmer bed battery pack making a 'strange noise' with emission of smoke during transport from the delivery room to the NICU. The infant was removed from the warmer and the O2 being delivered to the patient was turned off.
- An infant warmer was in use in the NICU for about 2 hours when a burning odor was noticed and smoke was observed coming from the top of the unit. No mention of patient injury. Follow-up reveals the power supply module was found to have fairly significant damage coming from components within the board. The components were replaced.

Lessons Learned from Adverse Events

- Use incubators and warmers according to manufacturer labeling and instructions for use.
- Make sure to use appropriate power cords and connections for the device, including batteries and battery packs.
- Regularly inspect power cords and connections to make sure they are not frayed, loose, or showing signs of heat wear or damage (i.e. signs of melting).
- Monitor oxygen delivery devices for proper function while in use.
- Schedule routine device/equipment inspections and adhere to a clearly defined maintenance/service plan to assure functional integrity of the device.

Recently Reported Adverse Event with Monitors

- GE Dash 4000 monitor display spontaneously goes blank or blacks out while in use on NICU patients. The displays remain off despite multiple attempts by clinicians. RN's unable to view ECG tracings and other hemodynamics on NICU patients. GE has provided loaner Dash 4000's during the time of the hospital's reported problem.

Recently Reported Adverse Event with Monitors

- Follow-up with the firm resulted in the firm's issuance of a product information letter to chiefs of nursing, directors of biomedical engineering and healthcare administrators.
- The letter alerts users to the display becoming unusable after several years of continuous operating service life.

Adverse Event Evaluation

- Reports are individually triaged to identify actual or potential risk to public health requiring priority review and follow-up
- Examples of high-risk events include events of :
 - pediatric deaths
 - multiple patient deaths or serious injuries
 - death involving
 - Fire , Explosion, Electrocution
 - Burn, Anaphylaxis, Exsanguination

Adverse Event Evaluation

Reports are then reviewed against previously submitted adverse event reports:

- In the MedSun database that contains reports received from other MedSun facilities
- In the MAUDE (Manufacturer and User Facility Device Experience database) that contains reports submitted by manufacturers, consumers, and user facilities (including MedSun) to further understand reported device problems

Adverse Event Evaluation

- A check of pre-market approval or clearance information is checked to obtain labeling and instructions for use
- Looking at the clinical and scientific literature reviews for information on the occurrence of similar problems with the device
- Independent safety research organization data may be researched to gain additional perspectives, i.e., ECRI, ISMP

Adverse Event Evaluation

Reviewers may request additional information about an individual event or a group of similar events by:

- Contacting the manufacturer, user facility or voluntary reporter via:
 - telephone, fax, letter, or e-mail

- Working with other CDRH Offices to arrange:
 - a manufacturing facility inspection to see how the device is made and how product complaints are handled
 - a user facility visit to talk with those involved in the adverse event

- Consulting with other FDA Centers to obtain additional perspectives on reported problems

Adverse Event Outcomes

- All data related to the adverse event are reviewed to determine if and what type of FDA action should be undertaken. Outcomes of adverse event evaluations include:
 - **Education and Outreach**
 - Articles in peer-reviewed clinical journals and Newsletters
 - Presentations at conferences
 - **Research Initiatives**
 - Initiation of surveys to further characterize device use in clinical settings
 - Partnering with organizations to create or access device-related adverse event registries
 - Working with standards organizations to develop or refine device standards
 - **Public Health Notifications**
 - Safety Alerts, CDRH web postings
 - **Regulatory Actions**
 - Recalls

Update on FDA Actions in Response to Heparin Adverse Events

- FDA Update on Contaminated Heparin
- <http://www.fda.gov/cder/drug/infopage/heparin/default.htm#healthcare>

Searching the Public Maude and MedSun Databases

Public Medical Device Adverse Event Databases

- Two public databases are available for searching medical device adverse event reports submitted to the FDA
- MedSun reports through MedSun's Online Newsletter access via:

<http://www.fda.gov/cdrh/medsun/index.html>

- Manufacturer, voluntary, and all user facility reports (including MedSun) through Public Maude access via:

<http://www.fda.gov/cdrh/maude.html>

Searching the MedSun Database from the MedSun Online Newsletter

The screenshot shows a Microsoft Internet Explorer browser window displaying the MedSun website. The browser's address bar shows the URL <http://www.fda.gov/cdrh/medsun/>. The website header features the FDA logo and the text "U.S. Food and Drug Administration" and "Department of Health and Human Services". Below the header, the "Medical Product Safety Network" is highlighted, with the "MedSun" logo to the right. A navigation menu on the left includes links for Home, About MedSun, Newsletters, MedSun Reports, Educational Materials, MedWatch Home, Medical Device Safety Home, Subscribe to Email Updates on MedSun, and Contact Us. The main content area displays the breadcrumb "FDA > CDRH > MedSun > MedSun Home Page" and the title "MedSun: Shining a Light on Medical Product Safety". A link to "Subscribe to Email Updates" is provided. The text explains that the MedSun Product Safety Network improves FDA's understanding of medical device safety concerns and provides public access to de-identified reports. A section for "Newsletter #23, April 2008" lists an article titled "Epidural Conduction Device Fractures and Complications of Retained Fragments" by Robert Fisher, MD, MCh, FDA Medical Device Safety Desk. The article is noted as reprinted from the American Association of Nurse Anesthetists. The browser's taskbar at the bottom shows the Windows Start button, several open applications, and the system clock displaying 8:24 AM.

Searching the MedSun Database from the MedSun Online Newsletter

- Double click on 'Reports' - found on the left hand side of the home page screen
- There are two methods of searching available to you:
 - Simple Search
 - Advanced Search

MedSun Simple Search

The screenshot shows a Microsoft Internet Explorer browser window displaying the MedSun Simple Search page. The browser's address bar shows the URL: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/searchReportText.cfm>. The page header features the FDA logo and the text "U.S. Food and Drug Administration" and "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH". Below the header is a navigation bar with links for "FDA Home Page", "CDRH Home Page", "Search", and "A-Z Index". The main content area is titled "Medical Product Safety Network" and "MedSun Reports". On the left side, there is a navigation menu with links for "Home", "About MedSun", "Newsletters", "Medsun Reports", "Educational Materials", "MedWatch Home", "Medical Device Safety Home", "Subscribe to Email Updates on MedSun", and "Contact Us". The main search area includes a "Search For" input field, a "Records per Report Page" dropdown menu set to "5", and a "Date Report Sent to FDA" dropdown menu with options for "ALL YEARS", "2008", "2007", "2006", and "2005". There are "Search", "Clear", and "Advanced Search" buttons. Below the search area, there is a note: "To further refine your search, select 'Advanced Search' to search by Manufacturer, Device Brand, Device Type, Event Description, Outcome, Date Range." The page is powered by Google. The Windows taskbar at the bottom shows the start button, several open applications, and the system clock displaying 3:52 PM.

US FDA/CDRH: MedSun: MedSun Reports - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/searchReportText.cfm>

FDA U.S. Food and Drug Administration Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [A-Z Index](#) [Questions?](#)

Medical Product Safety Network **MedSun**

FDA > CDRH > MedSun > MedSun Reports

MedSun Reports

Search For

Records per Report Page 5

Date Report Sent to FDA (press CTRL key for multiple years)

ALL YEARS
2008
2007
2006
2005

Search Clear Advanced Search

To further refine your search, select "Advanced Search" to search by Manufacturer, Device Brand, Device Type, Event Description, Outcome, Date Range.

powered by Google™

start 6 Micr... 2 Inte... 2 Micr... Local intranet 3:52 PM

MedSun Simple Search Results

The screenshot shows a Microsoft Internet Explorer browser window with the following details:

- Address Bar:** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/medsun_details.cfm?ID=%24%22%2DW%3D%27%40%20%20%0A
- Page Title:** US FDA/CDRH: MedSun: MedSun Reports - Microsoft Internet Explorer
- Navigation:** Back, Forward, Home, Search, Favorites, etc.
- Search Bar:** Manufacturer Device Brar
- Page Content:**
 - Breadcrumbs:** FDA > CDRH > MedSun > MedSun Reports
 - Section Header:** MedSun Reports
 - Navigation:** [Back To Search Results](#)
 - Device Information:**
 - Type of device:** Open bed infant warmer
 - Device brand name:** Air Shield
 - Device manufacturer's name:** Hill Rom/ Air Shield
 - Date of this report:** 12/16/2002
 - Describe the event or problem:** Temperature control failed on the solid-state relay heating elements on the bed warmers. The device would overheat, or not heat, or heat constantly with no alarms in any of these situations. The device should turn on or off depending on the infant's temperature detected by a probe. If the sensor didn't detect certain temperatures the infant would potentially be compromised by decreased or increased temperatures. The facility was told by the manufacturer that the service manual instructed them to replace the solid state relay on a routine basis but this requirement was not found by the facility in the booklet provided.
 - The device(s) may have caused or contributed to:** Potential for patient harm

MedSun Advanced Search

The screenshot shows a Microsoft Internet Explorer browser window displaying the MedSun website. The address bar shows the URL: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/searchReport.cfm>. The page title is "US FDA/CDRH: MedSun: Medsun Reports".

The main content area is titled "Medical Product Safety Network" and "Medsun Reports". The breadcrumb navigation is: [FDA](#) > [CDRH](#) > [MedSun](#) > Medsun Reports.

The search form includes the following fields and options:

- Manufacturer**: Text input field.
- Device Brand**: Text input field.
- Device Type**: Text input field.
- Event/Problem Description**: Text input field.
- The device(s) may have caused/contributed to:** A dropdown menu with the following options: "Any Cause or Contribution" (selected), "Death", "Serious injury", and "Potential harm to a health care provider".
- Date Report Sent to FDA Start Date**: Text input field with a calendar icon, containing "03/23/2008".
- Date Report Sent to FDA End Date**: Text input field with a calendar icon, containing "04/23/2008".
- A note below the date fields: "February 20, 2002 is the earliest date for searching Medsun Reports."
- Records per Report Page**: A dropdown menu set to "5".
- Search**: A button.
- Clear**: A button.
- Simple Search**: A button.

The left sidebar contains navigation links:

- Home
- About MedSun
- Newsletters
- Medsun Reports
- Educational Materials
- MedWatch Home
- Medical Device Safety Home
- Subscribe to Email Updates on MedSun
- Contact Us

The Windows taskbar at the bottom shows the Start button, several application icons, and the system tray with the time "8:33 AM" and "Local intranet" indicator.

MedSun Advanced Search Features

- Selecting the advanced search feature allows you to search by inputting one or more criteria in the text boxes denoted below:

Manufacturer

Device Brand

Event/Problem Description

Device Type

- The device(s) may have caused/contributed to:
 - Any cause or contribution
 - Death
 - Serious injury
 - Potential harm to health care provider
 - Minor injury to the patient or health care provider
 - Potential for patient harm

MedSun Advanced Search Features

(cont'd)

- Note: February 20, 2002 is the earliest date for searching MedSun Reports
 - Input date range with a beginning date
 - Input date range with an end date or the current date as necessary
 - Select records to be displayed per page
 - 5
 - 10
 - 25
 - 50

MedSun Pre-Programmed Reports: MedSun Search Results Presented in a Table

(based on your selected search criteria)

US FDA/CDRH: MedSun: MedSun Reports - Microsoft Internet Explorer

Address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm>

FDA U.S. Food and Drug Administration Department of Health and Human Services
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [A-Z Index](#) [Questions?](#)

Medical Product Safety Network **MedSun**

FDA > CDRH > MedSun > MedSun Reports

MedSun Reports

Search For

Records per Report Page 5

Date Report Sent to FDA
(press CTRL key for multiple years)

ALL YEARS
2008
2007
2006
2005

To further refine your search, select 'Advanced Search' to search by Manufacturer, Device Brand, Device Type, Event Description, Outcome, Date Range.

powered by Google™

Done Local intranet 12:24 PM

MedSun Advanced Search Results

(based on your selected search criteria)

The screenshot shows a Microsoft Internet Explorer browser window with the address bar displaying <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/searchReport.cfm>. The page title is "US FDA/CDRH: MedSun: Medsun Reports - Microsoft Internet Explorer". The browser's menu bar includes File, Edit, View, Favorites, Tools, and Help. The address bar contains a search bar and a "Go" button. The page content includes a navigation menu on the left with links to Home, About MedSun, Newsletters, Medsun Reports, Educational Materials, MedWatch Home, Medical Device Safety Home, Subscribe to Email Updates on MedSun, and Contact Us. The main content area shows the breadcrumb "FDA > CDRH > MedSun > Medsun Reports" and the heading "Medsun Reports". Below the heading, it states "5 records meeting your search criteria returned - *infant warmer 03/23/2002 04/23/2008*". A table with 5 columns is displayed, with headers: "New Search", "Export", "Device Brand", "Device Manufact.", "Device Type", "Caused/Contributed", and "Report Date". The table contains 5 rows of data. The Windows taskbar at the bottom shows the start button, several open applications, and the system tray with the time 12:46 PM.

FDA > CDRH > MedSun > Medsun Reports

Medsun Reports

5 records meeting your search criteria returned - *infant warmer 03/23/2002 04/23/2008*

New Search	Export	Device Brand	Device Manufact.	Device Type	Caused/Contributed	Report Date
Versalet		Drager Medical, Inc.	Infant Warmer/Incubator	Potential for patient harm	03/09/2005	
Versalet		Drager Medical, Inc.	Infant Warmer/Incubator	Potential for patient harm	03/09/2005	
Air Shield		Hill Rom/ Air Shield	Open bed infant warmer	Potential for patient harm	12/16/2002	
Air Shield		Hill Rom/Air Shield	Open bed infant warmer	Potential for patient harm	12/16/2002	
Infant Warmer		Fisher Paykel	[infant warmer]	Potential harm to a health care provider; Potential for patient harm	11/11/2002	

MedSun Advanced Search Results

(note that large sets of results will be displayed on multiple pages)

The screenshot shows a Microsoft Internet Explorer browser window with the address bar displaying <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm>. The page title is "US FDA/CDRH: MedSun: MedSun Reports". The main content area is titled "MedSun Reports" and shows search results for "Pulse oximeter".

Navigation links on the left include: About MedSun, Newsletters, Medsun Reports, Educational Materials, MedWatch Home, Medical Device Safety Home, Subscribe to Email Updates on MedSun, and Contact Us.

The search results section shows 39 records meeting the search criteria returned for "Pulse oximeter" out of 42. The number of records meeting the search criteria is greater than the system can return and is incomplete. Please narrow your search.

The results are displayed in a table with the following columns: Device Brand, Device Manufact., Device Type, Caused/Contributed, and Report Date. The table includes a "New Search" link and an "Export" button.

Device Brand	Device Manufact.	Device Type	Caused/Contributed	Report Date
Radical 7	Masimo Corporation	Monitor, Pulse Oximeter	Not applicable	01/18/2008
LNCS Neo-L	Masimo Corporation	sensor, pulse oximeter	Minor injury to the patient or health care provider	12/30/2007
Marquette Eagle 4000	GE Medical Systems Information Technologies	monitor, physiological	Potential for patient harm	11/16/2007
NPB 290:LTV 950	Covidien Nellcor;VIASYS Healthcare Medsystems/Pulmonetic Systems, Inc.	Pulse Oximeter;Ventilator	Death	10/26/2007
UCW:Radical	Spacelabs Healthcare, Inc.;Masimo Corporation	monitor, physiological;pulse oximeter	Potential for patient harm	09/10/2007

Public Maude

- MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19.
- The on-line search allows you to search CDRH database information on medical devices which may have malfunctioned or caused a death or serious injury. MAUDE is scheduled to be updated quarterly and the search page reflects the date of the most recent update. FDA seeks to include all reports received prior to the update. However, the inclusion of some reports may be delayed by technical or clerical difficulties.
- MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices. Please be aware that reports regarding device trade names may have been submitted under different manufacturer names. Searches only retrieve records that contain the search term(s) provided by the requester.

Search Criteria for Public Maude

- Input your search criteria into any of the following fields. Most have drop down dialog boxes to assist you with selecting search criteria:
 - Product Problem
 - Product Class
 - Brand Name
 - 510k Number
 - Manufacturer
 - PMA Number
 - Event Type
 - **Product Code ***a three-letter descriptor used to identify device type**
 - Date range
 - Number of records to be displayed per page
 - 5-10-25-50-100-500

Public Maude

FDA > CDRH > MAUDE Database Search - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>

MAUDE data represents r Find it Map It Reference Weather Ringtones '08 Credit Score Lose Weight Fast

2007 Credit Report Business Cards Reunion.com Search... Games Videos MyCursor zango

Search MAUDE Database

[Help](#) | [Download Files](#) | [More About MAUDE](#)

Enter one or a combination of the MAUDE Search Values and select Search

Product Problem

Product Class

Brand Name

Manufacturer

Event Type

510K Number

PMA Number

Product Code

Date Report Received by FDA (mm/dd/yyyy) to

For full-text search, select [Go To Simple Search](#) button

Records per Report Page

[Medical Device Reporting Search: \(for incidents before July 31, 1996\)](#)

Database last updated on March 27, 2008

[CDRH Home Page](#) | [CDRH A-Z Index](#) | [Contact CDRH](#) | [Accessibility](#) | [Disclaimer](#)
[FDA Home Page](#) | [Search FDA](#) | [Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [HHS Home Page](#)

Related Search: [beatrice maude](#) [bea arthur](#) [maude fealy](#) [harold and maude](#) [maude sitcom](#) [harold and maude movie](#) [television maude](#)

starware Help Snooze

Local intranet

start 2 M... Sea... I... 1:35 PM

Maude Database Simple Search

The screenshot shows a Microsoft Internet Explorer browser window displaying the MAUDE Database Simple Search page. The address bar shows the URL: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>. The page title is "FDA > CDRH > MAUDE Database Search - Microsoft Internet Explorer".

The main content area is titled "Search MAUDE Database" and includes the following elements:

- Navigation links: [Help](#) | [Download Files](#) | [More About MAUDE](#)
- Instructions: "Enter a search term below, choose a date range and select Search"
- Search input field: A text box for entering search terms.
- Search instructions: "Enter a single word (e.g., electromechanical), an exact phrase (e.g., electromechanical pump) or multiple words. To Search by Brand Name, Manufacturer, Event Type, S10K Number, PMA Number, Product Code, or date, select [Go To Advanced Search](#) button."
- Date range selection: "Date Report Received by FDA (press CTRL key for multiple years)" with a dropdown menu showing "ALL YEARS", "2008", "2007", "2006", and "2005".
- Search controls: "Go to Advanced Search" button, "10" records per page dropdown, "Records per Report Page", "Search" button, and "Clear" button.

Below the search area, there is a link for "Medical Device Reporting Search: *(for incidents before July 31, 1996)*" and a note: "Database last updated on March 27, 2008".

At the bottom of the page, there are several links: [CDRH Home Page](#) | [CDRH A-Z Index](#) | [Contact CDRH](#) | [Accessibility](#) | [Disclaimer](#) | [FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [HHS Home Page](#). The footer also includes "Center for Devices and Radiological Health / CDRH".

The browser's taskbar shows the Windows Start button, several application icons, and the system tray with the time "1:45 PM".

MAUDE Simple Search Results

(note the underlined text in search results table)

Manufacturer and User Facility Device Experience (MAUDE) Database Search - Microsoft Internet Explorer

Address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextResults.cfm>

Database

CFR Title 21 | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

1 2 3 4 5 6 7 8 9 10 >

about 502 records meeting your search criteria returned for *infusion pump 2008* out of 1100.
The number of records meeting your search criteria is greater than the system can return and is incomplete.
Please narrow your search.

Manufacturer	Brand Name	Date Report Received
ANIMAS CORP.	<u>ANIMAS INSULIN INFUSION PUMP</u>	03/24/2008
ANIMAS CORP.	<u>ANIMAS INSULIN INFUSION PUMP</u>	03/24/2008
ANIMAS CORP.	<u>ANIMAS INSULIN INFUSION PUMP</u>	03/24/2008
MEDTRONIC MINIMED	<u>PUMP MMT-512LWWS PRDGM INS SK EN LN</u>	03/21/2008
MEDTRONIC MINIMED	<u>PUMP MMT-515NAB PRDGM INS V2.1 BL E</u>	03/21/2008
MEDTRONIC MINIMED	<u>PUMP MMT-722CAL PRDGM INS V2.2 CL E</u>	03/21/2008
ANIMAS CORP.	<u>ANIMAS INSULIN INFUSION PUMP</u>	03/21/2008
ANIMAS CORP.	<u>ANIMAS INSULIN INFUSION PUMP</u>	03/21/2008
ANIMAS CORP.	<u>ANIMAS INSULIN INFUSION PUMP</u>	03/21/2008
MEDTRONIC PUERTO RICO OPE	<u>PUMP MMT-722WWL PRDGM INSULIN CL EN</u>	03/21/2008

Related Search: [beatrice maude](#) [bea arthur](#) [maude fealy](#) [harold and maude](#) [maude sitcom](#) [harold and maude movie](#) [television maude](#)

Help Snooze

Display Individual MAUDE Reports from Simple Search Results

(click on underlined text in search results table)

The screenshot shows a Microsoft Internet Explorer browser window with the address bar displaying http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1018843. The browser's address bar also shows a search for "Database". The page content includes the FDA logo and the text "U.S. Food and Drug Administration" and "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH". Below this, there are navigation links for "510(k)", "Registration & Listing", "Adverse Events", "PMA", "Classification", "CLIA", "CFR Title 21", "Advisory Committees", "Assembler", "Recalls", "Guidance", and "Standards". The main content area is titled "Adverse Event Report" and contains the following information:

ANIMAS CORP. ANIMAS INSULIN INFUSION PUMP [back to search results](#)

Model Number IR 1250
Event Date 02/20/2008
Event Type Injury **Patient Outcome** Hospitalization;
Event Description
The pt was hospitalized for hypoglycemia and seizure.

Manufacturer Narrative
The pump has not been returned to animas for evaluation. Evaluation demonstrated that the pump was operating within required specifications and delivery accuracy.

[Search Alerts/Recalls](#)

At the bottom of the browser window, there is a "Related Search" section with the following links: [beatrice maude](#), [bea arthur](#), [maude fealy](#), [harold and maude](#), [maude sitcom](#), [harold and maude movie](#), and [television maude](#). The browser's taskbar shows the "start" button and several open applications, including "Inb...", "Sea...", and "Ma...". The system tray shows the time as 2:27 PM.

MAUDE Advanced Search

The screenshot shows a Microsoft Internet Explorer browser window displaying the MAUDE Database Search page. The address bar shows the URL: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>. The page title is "FDA > CDRH > MAUDE Database Search - Microsoft Internet Explorer".

The main content area is titled "Search MAUDE Database" and includes a search form with the following fields:

- Product Problem (dropdown menu)
- Product Class (dropdown menu)
- Brand Name (text input)
- Manufacturer (text input)
- Event Type (dropdown menu)
- 510K Number (text input, value: K)
- PMA Number (text input, value: P)
- Product Code (text input)
- Date Report Received by FDA (mm/dd/yyyy) (range: 01/01/2008 to 03/27/2008)

Below the search form, there is a "Go to Simple Search" button, a "Records per Report Page" dropdown menu set to "10", a "Search" button, and a "Clear" button. A note below the form reads: "For full-text search, select Go To Simple Search button".

At the bottom of the search area, there is a link: [Medical Device Reporting Search: \(for incidents before July 31, 1996\)](#) and a status message: "Database last updated on March 27, 2008".

The footer of the page contains several links: [CDRH Home Page](#), [CDRH A-Z Index](#), [Contact CDRH](#), [Accessibility](#), and [Disclaimer](#). There is also a "Related Search" section with suggestions like "beatrice maude", "maude fealy", "maude sitcom", and "television maude".

The Windows taskbar at the bottom shows the Start button, several application icons, and the system tray with the time "1:35 PM".

What Product Code to Enter?

- You can query the Product Code database if you are unclear on which product code to enter into your search criteria
- You will be redirected to the Product Code database
- Or you can search the Product Code database via this link:
 - <http://www.fda.gov/cdrh/Productcode.html>
- Enter in search terms to utilize this database

Product Code Database

The screenshot shows a Microsoft Internet Explorer browser window displaying the US FDA/CDRH Product Code Classification Database. The address bar shows the URL <http://www.fda.gov/cdrh/Prodcode.html>. The page header features the FDA logo and the text "U.S. Food and Drug Administration" and "Department of Health and Human Services". Below the header, there are navigation links for "FDA Home Page", "CDRH Home Page", "Search", and "A-Z Index". The main content area is titled "Product Code Classification Database" and includes a description of the database's purpose and a list of links for searching and downloading files. The browser's taskbar at the bottom shows the Windows Start button, several application icons, and the system clock displaying 1:40 PM.

US FDA/CDRH: Product Code Classification Database - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://www.fda.gov/cdrh/Prodcode.html>

Database Find it Map It Reference Weather Ringtones '08 Credit Score Lose Weight Fast

2007 Credit Report Business Cards Reunion.com Search... Games Videos MyCursor zango

FDA U.S. Food and Drug Administration Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [A-Z Index](#) [Questions?](#)

[FDA](#) > [CDRH](#) > [Product Classification Database](#) > Product Code Classification Database

Product Code Classification Database

Product Code Classification Database

[Registration & Listing Home](#)

The [Product Classification Database](#) contains medical device names and associated information developed by the Center for Devices and Radiological Health (CDRH) in support of its mission. This database contains device names and their associated product codes. The name and product code identify the generic category of a device for FDA. The Product Code assigned to a device is based upon the medical device product classification designated under 21 CFR Parts 862-892.

These files are updated monthly, usually on the 6th of each month.

- [Search the on-line product code database](#)
- [Information on how to classify a device](#)
- [Download Product Code files](#)

Information on Devices Regulated by other Centers

Related Search	beatrice maude	maude fealy	maude sitcom	television maude	Help
starware	bea arthur	harold and maude	harold and maude movie		Snooze

start Local intranet 1:40 PM

Neonatal Product Codes

- FMT - warmer, infant radiant
- FMZ - incubator, neonatal
- FPL – incubator, neonatal transport
- LBI – phototherapy unit, neonatal
- FOS – catheter, umbilical artery
- HIQ – electrode, fetal scalp
- FLS- monitor, apnea, facility-use
- FOK – pad, neonatal eye

Pediatric Product Codes

- **FFH** – collector, urine, pediatric, for indwelling catheter
- **FMS** – bed, pediatric open-hospital
- **FNC** – tent, pediatric aerosol
- **GBN** – catheter, pediatric, general & plastic surgery
- **KKO** – ring, teething, fluid-filled
- **OBT** – plate, bone, growth control, pediatric, epiphysiodesis
- **OFP** – anesthesia breathing circuit kit (adult & pediatric)

MAUDE Advanced Search Results

(note the underlined text in search results table)

FDA > CDRH > MAUDE Database Search - Microsoft Internet Explorer

Address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Results.cfm?RequestTimeout=500>

48 records meeting your search criteria returned - ProductCode: "fmt" ReportDateFrom: "01/01/2005" ReportDateTo: "03/27/2008"

[New Search](#) [Help](#) | [Download Files](#) | [More About MAUDE](#)

Manufacturer	Brand Name	Date Report Received
DRAEGER MEDICAL SYST	<u>RESUSCITAIRE RW82/WB</u>	02/08/2008
DRAEGER MEDICAL SYST	<u>RESUSCITAIRE</u>	10/25/2007
DRAEGER MEDICAL SYST	<u>RESUSCITAIRE RADIANT</u>	10/17/2007
FISHER & PAYKEL HEAL	<u>INFANT WARMER HEAD A</u>	10/11/2007
FISHER & PAYKEL HEAL	<u>COSYCOT INFANT WARME</u>	10/05/2007
FISHER & PAYKEL HEAL	<u>COSYCOT INFANT WARME</u>	10/05/2007
FISHER & PAYKEL HEAL	<u>COSYCOT INFANT WARME</u>	10/05/2007
FISHER & PAYKEL HEAL	<u>COSYCOT INFANT WARME</u>	10/05/2007
FISHER & PAYKEL HEAL	<u>COSYCOT INFANT WARME</u>	09/16/2007
FISHER & PAYKEL HEAL	<u>COSYCOT INFANT WARME</u>	09/04/2007
FISHER & PAYKEL HEAL	<u>COSYCOT</u>	08/04/2007

Database last updated on March 27, 2008

Related Search: [beatrice maude bea arthur](#) | [maude fealy harold and maude](#) | [maude sitcom harold and maude movie](#) | [television maude](#)

start | Inb... | Sea... | FD... | Local intranet | 1:56 PM

Display Individual MAUDE Reports from Advanced Search Results

(click on underlined text in search results table)

Manufacturer and User Facility Device Experience (MAUDE) Database Search - Microsoft Internet Explorer

Address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=996580

DRAEGER MEDICAL SYSTEMS, INC. (P) (U) (M) (R) (W) (R) (B) (R) (8) (2) (I) (N) (F) (A) (N) (T) (R) (A) (D) (I) (A) (N) (T) (W) (A) (R) (M) (E) (R) [back to search results](#)

Model Number RW82
Event Date 01/03/2008
Event Type Injury **Patient Outcome** Required Intervention;
Event Description
It was reported that: a nine month old baby was placed in a rw82 for about 30 mins using the manual mode. During this time, the baby was slightly burned.

Manufacturer Narrative
The customer has not allowed draeger to inspect the device. It was reported that the unit was being used in the manual heating mode. In this mode, the user should constantly observe the infant, and monitor the infant temperature to avoid over heating or under heating. The device is designed so that when in manual mode if the warmer is in operation for longer than 10 mins, the check pt indicator illuminates and the alarm sounds. The indicator remains illuminated, and the alarm continues to sound every 30 seconds for 5 mins or until the user acknowledges the alarm. If the alarm has not been acknowledged for a total of 15 mins, the heater will shut off and a three level alarm sounds continuously. The user must acknowledge this alarm to restart the heater output. The investigation has not determined any product malfunction. The reported pt injury may potentially be due to user error.

[Search Alerts/Recalls](#)

[new search](#) | [submit an adverse event report](#)

Related Search: [beatrice maude](#), [bea arthur](#), [maude fealy](#), [harold and maude](#), [maude sitcom](#), [harold and maude movie](#), [television maude](#), [starware](#)

(4 items remaining) Downloading picture http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/images/fda_cdrh_02.gif... Local intranet

1:57 PM

Availability of Maude Adverse Events for Downloading onto your Computer

US FDA/CDRH: Manufacturer and User Facility Device Experience Database (MAUDE): File Formats fo - Microsoft Internet Explorer

Address: <http://www.fda.gov/cdrh/maude.html#files>

The following files are available: (File Sizes are approximate)

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
MDRFOI.ZIP	1837KB	13359KB	40601	MAUDE Base records received to date for 2008
MDRFOIADD.ZIP	577KB	4323KB	13201	New MAUDE Base records for the current month.
MDRFOICHANGE.ZIP	479KB	3565KB	11012	MAUDE Base data updates: changes to existing Base data.
MDRFOITHRU2007.ZIP	40595KB	284400KB	926872	Master Record through 2007
PATIENT.ZIP	456KB	2183KB	40672	MAUDE Patient Records received to date for 2008
PATIENTADD.ZIP	135KB	611KB	13220	New MAUDE Patient data for the current month.
PATIENTCHANGE.ZIP	124KB	549KB	11031	Maude Patient data updates: changes to existing Patient data and additional Patient data for existing Base records.
PATIENTTHRU2007.ZIP	6672KB	33708KB	930368	MAUDE Patient Records through 2007
DEVICEPROBLEMCODES.ZIP	8KB	21KB	825	Device Problem Codes
FOIDEV2000.ZIP	2953KB	15229KB	53299	Device Data for 2000
FOIDEV2001.ZIP	3188KB	16360KB	58074	Device Data for 2001
FOIDEV2002.ZIP	3380KB	17361KB	65812	Device Data for 2002
FOIDEV2003.ZIP	3542KB	18053KB	67847	Device Data for 2003
FOIDEV2004.ZIP	3037KB	14973KB	57057	Device Data for 2004
FOIDEV2005.ZIP	4644KB	24826KB	93510	Device Data for 2005

Related Search: [beatrice maude](#), [bea arthur](#), [maude fealy](#), [harold and maude](#), [maude sitcom](#), [harold and maude movie](#), [television maude](#)

Done

start Inb... Sea... US ... Local intranet 1:59 PM

Summary

- Both public databases (MedSun and MAUDE) are accessed via the Internet Explorer
- All information contained in these databases falls under the Freedom of Information Act
- Results can be printed to your local printer