

# MedSun Database Screenshots

April 2020



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# MedSun Login Page



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### MedSun Login

**User ID:**  [Forgot User ID](#)

**Password:**  [Forgot Password](#)



*I agree to FDA System Use Notification:*

### FDA System Use Notification

This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.

- This system is provided for Government-authorized use only.
- Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties.
- Personal use of social media and networking sites on this system is limited as to not interfere with official work duties and is subject to monitoring.
- By using this system, you understand and consent to the following:
  - The Government may monitor, record, and audit your system usage, including usage of personal devices and email systems for official duties or to conduct HHS business. Therefore, you have no reasonable expectation of privacy regarding any communication or data transiting or stored on this system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this system.
  - Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

# Home Page



---

[Home](#) [Browse/Edit](#) [Add Report](#) [Analysis](#) [Messages](#) [Options](#) [Resources](#) [Logout](#)

Thursday, October 5, 2017


## Welcome back, Mr. Reporter!

Last Login: 10/5/2017 9:49:18 AM EST

**Special Note:** Special note on MedSun landing page for Facility user


- You have **1** message topics that need your response [View messages needing your response »](#)
- You have **2** unread messages [View unread messages »](#)
- You have **19** reports that you are still working on (*not ready to submit*) [View reports »](#)
- You have **2** reports that are ready to submit to the FDA [View reports »](#)

### MedWatch Safety Alert

 **Intraocular Injections of a Compounded Triamcinolone, Moxifloxacin, and Vancomycin (TMV) Formulation: FDA Statement - Case of Hemorrhagic Occlusive Retinal Vasculitis**

10/3/2017

Prophylactic use of intraocular vancomycin, alone or in a compounded drug, during cataract surgery is generally not recommended because of the risk of HORV. [Read More »](#)

 **Infant Sleep Positioners: FDA**



BROWSE ALL

Find:  Search Browse By: --Show All-- [Go](#)  
Date Created  
Facility  
Tracking Status: In Progress  
Tracking Status: Ready to Submit  
50

(999) record(s) found.

Go To Page: First << < (1) 2 3 4 5 6 7 8 9 10 11 12 13 14 15 > >> Last

[View Report](#) **Report:** 0333020000-2017-8012 **UID:** 333012 **Status:** Completed  
**Facility:** Test Hospital **Date Submitted:** 10/11/2017 3:26:35 PM  
**Networks:** General Medsun **Report Documents:** [0](#)  
**Created:** 8/18/2017 3:22:16 PM **By** Mr. Reporter

[Print 3500A](#) **Messages:**  
[Print Summary](#) (0) unread (0) awaiting response (1) total

**Event Title:**  
description

**Event Description:**  
Please enter a brief (20 character) description to help you identify this report. You may want to use your hospital's event ID, or a few words describing the event, the situation, or the result of the event (monitor failure, ER catheter prob, or CCU death, for example), or anything else you like. The event title does not appear on the 3500A, but will appear in the report list on the Browse and Edit pages of MedSun, and is here to help you find the report you're looking for.

[Messages](#)

**Devices:** (1)  
1 Coronary drug-eluting stent, XIENCE ALPINE

[View Report](#) **Report:** 0333020000-2017-8011 **UID:** 333011 **Status:** In Progress  
[Edit Report](#) **Facility:** Test Hospital **Date Submitted:** (not submitted)  
**Networks:** General Medsun **Report Documents:** [1](#)  
**Created:** 8/18/2017 2:59:02 PM **By** Mr. Reporter

[Print 3500A](#) **Event Title:**  
[Print Summary](#) (no event title available)

**Event Description:**  
testins

[Submit to FDA](#) **Devices:** (1)  
1 device 1, (no Device Brand)

[View Report](#) **Report:** 0333020000-2017-8010 **UID:** 333010 **Status:** Complete/Ready to Submit  
[Edit Report](#) **Facility:** Test Hospital **Date Submitted:** (not submitted)  
**Networks:** General Medsun **Report Documents:** [0](#)  
**Created:** 8/18/2017 2:49:16 PM **By** Mr. Reporter

[Print 3500A](#) **Event Title:**  
[Print Summary](#) (no event title available)

**Event Description:**  
(no event description available)

[Submit to FDA](#) **Devices:** (0)  
(no device information available)



- Edit Report
- Submit To FDA
- Print 3500A
- Print Summary
- Printer Friendly
- View as MS Excel
- View as CSV

**0333020000-2017-8012**  
UNIQUE ID: 333012

**Submitted By:** Test Hospital

**EVENT**

**Event title: (short description to help you identify this event)**

description

# Adverse Event Report

Edit Report OMB Statement



[Home](#) [Browse/Edit](#) [Add Report](#) [Analysis](#) [Messages](#) [Options](#) [Resources](#)

[Logout](#)



- Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
- Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of the Chief Information Officer (HFA-250)  
5600 Fishers Lane  
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not allowed to respond to, a collection of information unless it displays a currently valid OMB control number.

- **FORM FDA 3670(05/17)**  
**OMB Number: 0910-0471**  
**Expiration date: 6/30/2020**

[Enter the report form](#)

## Edit Report Navigation

The screenshot shows the top navigation bar of the MedSun system. On the left is the MedSun logo with the tagline 'Medical Product Safety Network'. In the center, it says 'Create New Report Test Hospital'. On the right is the FDA U.S. Food & Drug Administration logo. Below this is a yellow navigation bar with the following tabs: 'Contact Info', 'Event', 'Patient', 'Device', 'Test', and 'Attachment'. A vertical sidebar on the left contains the following options: 'USER FACILITY', 'Save & Continue', 'Save & Exit', 'Submit To FDA', 'Cancel', and 'Set Report Status'.

## Edit Set Report Status

The dialog box is titled 'Set Report Status' and contains the following text: 'Please select a status from the list below:'. It then states 'The current status of this report is: READY TO SUBMIT'. There are two radio button options: 'IN PROGRESS' (unselected) and 'READY TO SUBMIT' (selected). The 'READY TO SUBMIT' option has a detailed description: 'You have finished the report and it needs to be reviewed by someone at your facility who will submit it to the FDA. **Please notify the reviewer** that the report is ready for review and submission.' At the bottom of the dialog are two buttons: 'Cancel' and 'Save Report Status'. A note at the bottom reads: 'NOTE: report status will change the next time you save the report.'


## Edit Report Submit


The screenshot shows a yellow success message box with the following text: 'SUBMIT REPORT' in bold blue letters, followed by 'Report was submitted to FDA successfully' in green text. Below this is a blue link that says '[close window]'.



# Contact Info

Edit/Add Report "Contact Infor"

**Create New Report**  
Test Hospital



[Contact Info](#) | [Event](#) | [Patient](#) | [Device](#) | [Test](#) | [Attachment](#)

**USER FACILITY**

Save & Continue

Save & Exit

Cancel

### CONTACT INFORMATION

**User facility name:**

**Address:** [limit: 50 lines of text]

**Contact's name:**

**Contact's phone number:**

**Contact's fax number:**

**Contact's email address:**

**Occupation of Contact:**

**Name of initial reporter:**

**Address of initial reporter:** [limit: 50 lines of text]

[Back To Top](#)



Contact Info Event Patient Device Test Attachment

USER FACILITY

Save & Continue

Save & Exit

Cancel

### CONTACT INFORMATION

Select a clinic:

- Test Hospital
- Testing Site
- Test Hospital

User facility name:

Event

Edit/Add Report "Event"

USER FACILITY

Save & Continue

Save & Exit

Cancel

EVENT INFORMATION

Event title: (short description to help you identify this event) ?

When did the event happen? (mm/dd/yyyy) ?

How many days ago did you first become aware of the event? ?

less than or equal to 10 days ago

more than 10 days ago

Date of this report: (mm/dd/yyyy) ?

Where did this event occur? ?

Hospital

Nursing home

Outpatient diagnostic facility

Laboratory not within a hospital

Not known

Other

Home

Outpatient treatment facility

Ambulatory surgical facility

Physician's office

Not applicable

The device(s) may have caused or contributed to: (Check all that apply) ?

Death

Serious injury

Potential harm to a health care provider [Indicates voluntary report]

Minor injury to the patient or health care provider [Indicates voluntary report]

Potential for patient harm [Indicates voluntary report]

Not known

Not applicable

Was there a problem with the device (such as a defect, malfunction, break, etc)? ?

Yes

Not known

No

Not applicable

Was someone directly "operating" the device at the time of the event? ?

Yes

Not known

No

Not Applicable

Were there other devices being used on the patient at the time of the event that may have caused or contributed to the event? [limit: 50 lines of text] ?

Were there other therapies being used on the patient at the time of the event that may have caused or contributed to the event? (Check all that apply) ?

Cardiac Drugs

Dialysis

Long-Term Antibiotics

Other

Not known

Chemotherapy

Immunotherapy

Prenatal medication

No other therapies


Not applicable

Describe the event or problem. Please provide as much detail as possible. [limit: 50 lines of text] ?


What was the original intended procedure? ?

Back To Top

Add Report Event with Network Pick (used by few sites)



**Create New Report**  
Test Hospital



Contact Info Event Patient Device Test Attachment

**USER FACILITY**

Save & Continue


Save & Exit

Cancel


### EVENT INFORMATION

**This MedSun report is a subnetwork report from: [Required]**


- (this is not a subnetwork report)
- HeartNet
- LabNet
- KidNet

Event title: (short description to help you identify this event) 



Add Report Event Follow Up Where2




**Create New Report**  
Test Hospital



### FOLLOW-UP QUESTIONS



Area where the event took place: [Optional]  

<input type="radio"/> Patient Room	<input type="radio"/> Critical Care
<input checked="" type="radio"/> OR	<input type="radio"/> ER
<input type="radio"/> NICU	<input type="radio"/> PICU
<input type="radio"/> Electrophysiology Lab	<input type="radio"/> Skilled Nursing Unit
<input type="radio"/> Other	<input type="radio"/> Not known
<input type="radio"/> Not applicable	


If you selected "Other" from the above menu, please specify where the event took place in the hospital. 

Cancel Save »

Add Report Event Follow Up Other Location



 **Create New Report**  
Test Hospital 

**FOLLOW-UP QUESTIONS**


Other location of event: [Optional] 


  
 

Add Report Event Follow Up Death

 **Create New Report**  
Test Hospital 



**FOLLOW-UP QUESTIONS**

Date of death: (mm/dd/yyyy) 


 




### FOLLOW-UP QUESTIONS

Was intervention required to prevent permanent impairment or damage?  

- Yes
- No
- Not known
- Not applicable

Outcomes attributed to serious injury: (Check all that apply) 

- Life-threatening
- Hospitalization, initial or prolonged
- Congenital anomaly
- Disability
- Other
- Not known
- Not applicable


If you checked "Other" above, please describe the outcome. 

Cancel

Save »



### FOLLOW-UP QUESTIONS

What problem did the user have (Check all that apply) [Optional] 

- Device failed (e.g. broke, couldn't get it to work or stopped working)
- Device malfunction - that is, the device did not do what it was supposed to do
- Device was hard to use
- Other
- Not known
- Not Applicable

Cancel

Save »



### FOLLOW-UP QUESTIONS

Who was operating the device? (Check all that apply) [Optional] ?

- |   |  |
|---|--|
| <input type="checkbox"/> Doctor                 | <input type="checkbox"/> Nurse                   |
| <input type="checkbox"/> Allied Health Provider | <input type="checkbox"/> Family Member / Visitor |
| <input type="checkbox"/> Patient                | <input type="checkbox"/> Other                   |
| <input type="checkbox"/> Not known              | <input type="checkbox"/> Not applicable          |

If you selected "Other" above, please describe the type of person who was operating the device. Do not give the person's name. ?

Cancel

Save »





### FOLLOW-UP QUESTIONS

List other therapies used on the patient at the time of the event that may have caused or contributed to the event: [limit: 50 lines of text] ?

Cancel


Save »






 **Create New Report**  
Test Hospital 

---

**FOLLOW-UP QUESTIONS**


Date of dialysis: (mm/dd/yyyy) 




 **Create New Report**  
Test Hospital 

---

**FOLLOW-UP QUESTIONS**

Date of chemotherapy: (mm/dd/yyyy) 



Help you find the report you're looking for.

es:  
ro

**SUBMIT REPORT**

**Empty event description not allowed. You must provide an event description before you can submit the report to the FDA.**


[\[close window\]](#)

te/  
d:  
en

Title:

# Patient

Edit/Add Report "Patient List" Empty



**Create New Report**  
Test Hospital



**Contact Info** **Event** **Patient** **Device** **Test** **Attachment**

**USER FACILITY**

Save & Continue

Save & Exit

Cancel


## PATIENT LIST

Enter new Patient information...

Edit/Add Report "Patient List" Empty



**Create New Report**  
Test Hospital



**Contact Info** **Event** **Patient** **Device** **Test** **Attachment**

**USER FACILITY**

Save & Continue

Save & Exit

Cancel

## PATIENT LIST

Enter new Patient information...

[Modify](#) [Remove](#) **Patient**




## PATIENT INFORMATION

**Patient identifier:** (DO NOT USE the patient's name, initials, social security number, date of birth, medical record number or other personal identifiers) ?

(Please limit your response to 8 characters)

**Patient's age at time of event:** ?

- Years
- Months
- Weeks
- Days
- DOB
- Do not know
- Not applicable

**Patient's gender:** ? 

- Male
- Female
- Not known
- Not applicable

**Patient's weight:** (select unit or "do not know") ?

- Kilograms
- Pounds
- Grams
- Ounces
- Do not know
- Not applicable

**Patient's race and ethnic background (check all that apply):** [Optional] ?

- American Indian or Alaskan Native
- Asian
- Black or African American
- Hispanic or Latino
- Native Hawaiian or other Pacific Islander
- White
- Unknown
- Not applicable

**Did the patient have any of the following preexisting characteristics that may have contributed to the event? (Check all that apply)** ?

- Allergies
- Alcohol/drug use
- COPD
- Coronary heart disease
- Diabetes
- Hepatic/renal dysfunction
- Hypertension
- Immuno-compromised
- Morbidly obese
- Pneumonia
- Pregnancy
- Premature infant
- Smoking
- Stroke
- Surgery
- Relevant accidents (e.g. Hit head)
- Other
- No preexisting characteristics
- Not known
- Not applicable

**Please provide any other information about the patient that may have influenced the outcome of the event. [limit: 50 lines of text]** ?



↑

↓

Cancel


Save »

Add Report Patient Pick DOB

Patient's gender  

### DATE OF BIRTH



Provide the date of birth in the box below, then click the SAVE button.




(mm/dd/yyyy)

Black or African American  Hispanic or Latino



Add Report Patient Follow Up Allergies

Create New Report  
Test Hospital **U.S. FOOD & DRUG  
ADMINISTRATION**

### FOLLOW-UP QUESTIONS


Please list the relevant patient allergies. (For example, latex allergy; a particular medication allergy; allergy to a particular material or biomaterial, etc.)  [limit: 50 lines of text]

Add Report Patient Follow Up Relevant accidents



 **Create New Report**  
Test Hospital 

---

**FOLLOW-UP QUESTIONS**


Please describe the relevant accident preceding the event. 

Add Report Patient Follow Up Other


 **Create New Report**  
Test Hospital 


---

**FOLLOW-UP QUESTIONS**

Other characteristics or medical conditions: [Optional] 

Edit Report Submit Missing Patient

Message from webpage 

 **WARNING: There is no PATIENT INFORMATION provided.**  
Click 'OK' to enter patient data or click 'CANCEL' to skip

Device

Edit/Add Report "Device List" Empty

The screenshot shows the MedSun 'Create New Report Test Hospital' interface. At the top left is the MedSun logo (Medical Product Safety Network). At the top right is the FDA U.S. FOOD & DRUG ADMINISTRATION logo. Below the header is a yellow navigation bar with tabs: Contact Info, Event, Patient, Device, Test, Attachment. The 'Device' tab is selected. On the left is a 'USER FACILITY' sidebar with buttons: Save & Continue, Save & Exit, and Cancel. The main area is titled 'DEVICE LIST' and contains a single button: 'Enter new Device information...'. A yellow bar is at the bottom of the interface.

Edit/Add Report "Device List"

The screenshot shows the MedSun 'Create New Report Test Hospital' interface with one device entry. The layout is identical to the previous screenshot, but the 'DEVICE LIST' now contains one entry: 'Device 1'. Above this entry is a button: 'Enter new Device information...'. Below the entry are three links: 'Modify', 'Remove', and 'Copy'. A yellow bar is at the bottom of the interface.





### DEVICE INFORMATION

Unique Device Identifier (UDI):  [Parse UDI into DI and PI fields](#)

Type of device:

Device manufacturer's name:

Device manufacturer's street address: (Line 1)

Street address: (Line 2)

City:

State:  (Please limit your response to 2 characters)

Zip:

Device brand name:

Approximate age of device:  Years

If a disposable device, was the packaging saved? [Optional]  Yes  No  Not known  Not applicable

Is this a single use device that was reprocessed and reused on a patient?  Yes  No  Unknown

Is this a laboratory device or laboratory test?  Yes  No

Device Identifier (DI):  [Query AccessGUDID](#)

Device serial #:  (Please limit your response to 30 characters)

Device model #:

Device lot #:  (Please limit your response to 30 characters)

Device catalog (REF) #:  (Please limit your response to 30 characters)

Other device #:

Expiration date: (mm/dd/yyyy)

If the device was implanted, give implant date: (mm/dd/yyyy)

If the device was explanted, give explant date: (mm/dd/yyyy)

Was the device returned to the manufacturer?  Yes  No  Not known  Not applicable

Is the device involved in this event available at your facility for evaluation?  Yes  No  Not known  Not applicable

Have you made the manufacturer aware of this problem/issue?  Yes  No  Unknown

## Add Report Device GUDID Parse

DEVICE: **XIENCE ALPINE (08717648200274)**  
DEVICE DESCRIPTION: **XIENCE Alpine Everolimus Eluting Coronary Stent System 3.50 mm x 28 mm / Over-The-Wire**

[UNSELECT ALL](#) [GO TO AccessGUDID](#)


These are device fields available in GUDID. Please select all fields you want to import into MedSun.

**DEVICE IDENTIFIER (DI) INFORMATION**

<input checked="" type="checkbox"/> Brand Name:	XIENCE ALPINE
<input checked="" type="checkbox"/> Version or Model:	1145350-28
<input checked="" type="checkbox"/> Catalog Number:	1145350-28
<input checked="" type="checkbox"/> Company Name:	ABBOTT VASCULAR INC.

**PARSED UDI INFORMATION**

<input checked="" type="checkbox"/> Device Identifier:	08717648200274
Donation ID:	A999713123456
<input checked="" type="checkbox"/> Lot Number:	00000000000XYZ123
<input checked="" type="checkbox"/> Serial Number:	000025
<input checked="" type="checkbox"/> Exp Date:	02/01/2014

**DEVICE TYPE** 

Select	Device Type
<input checked="" type="radio"/>	Coronary drug-eluting stent

[Submit](#) [Cancel](#)

## Add Report Device GUDID Query


DEVICE: **XIENCE ALPINE (08717648200274)**  
DEVICE DESCRIPTION: **XIENCE Alpine Everolimus Eluting Coronary Stent System 3.50 mm x 28 mm / Over-The-Wire**

[UNSELECT ALL](#) [GO TO AccessGUDID](#)

These are device fields available in GUDID. Please select all fields you want to import into MedSun.

**DEVICE IDENTIFIER (DI) INFORMATION**

<input checked="" type="checkbox"/> Brand Name:	XIENCE ALPINE
<input checked="" type="checkbox"/> Version or Model:	1145350-28
<input checked="" type="checkbox"/> Catalog Number:	1145350-28
<input checked="" type="checkbox"/> Company Name:	ABBOTT VASCULAR INC.

**DEVICE TYPE** 

Select	Device Type
<input checked="" type="radio"/>	Coronary drug-eluting stent

[Submit](#) [Cancel](#)



### FOLLOW-UP QUESTIONS

Enter name of reprocessor:

Reprocessor's street address (line 1):

Reprocessor's street address (line 2):

City:

State:

*(Please limit your response to 2 characters)*

Zip:

Cancel

Save »



### FOLLOW-UP QUESTIONS

Did this problem involve (check all that apply): ?

- The reagent
- Single use or rapid test
- The instrument
- Other

If you answered 'Other' to the question above, please specify in the text below: ?

Is this a recurrent problem with this assay, test kit or instrument? ?

- Yes
- No

If you answered 'YES' to the question above, please provide additional comments in the text below: ?

### Add Report Device Follow Up LabDevice\_2

Which of the following problems did you observe? (Check all that apply) ?

- Calibration
- Reproducibility
- Analytical specificity
- Questionable patient results
- Inadequate or unclear instructions for use
- Performance described in package insert not met
- Patient related problems
- Repeated error message
- Analytical sensitivity
- Quality Control
- Reagent(s)
- Poor test/instrument design
- Specimen problems
- Other

If you answered 'Other' to the question above, please provide additional comments in the text below: ?

### Add Report Device Follow Up LabDevice\_3



Please describe any follow up actions below (check all that apply) ?

- Repeated assay, results OK, reported out
- Replaced reagents
- Manufacturer notified
- Product not available to return to manufacturer
- Not known
- Other
- Repeated assay, still problems
- Opened new lot
- Called for service, received adequate response from manufacturer
- Discontinued all use of product
- Not applicable

If you answered 'Other' to the question above, please provide additional information below: ?


Cancel


Save »



 **Create New Report**  
Test Hospital 

---

### FOLLOW-UP QUESTIONS


**When do you plan to return the device to the manufacturer? [Optional]** 






 **Create New Report**  
Test Hospital 

---


### FOLLOW-UP QUESTIONS

**Date the device was returned to the manufacturer: (mm/dd/yyyy)** 



**How was the device returned to the manufacturer?**  

- Returned to the manufacturer by mail
- Given to manufacturer field representative
- Other method

**If you answered 'OTHER METHOD' in the question above, please provide additional comments below.** 



### FOLLOW-UP QUESTIONS

What has been the manufacturer's response? (please limit your response to 50 lines of text)

Can this information be made available to the public?

Yes

No

Cancel

Save »



### FOLLOW-UP QUESTIONS

Do you intend to return the device to the manufacturer in the near future? [Optional]

Yes

No

Where is the device now?

- Retained by the patient or patient representative
- Discarded
- Retained by the hospital
- Other

If you answered 'OTHER' in the question above, please provide additional comments below.

Cancel

Save »

Edit Report Submit Missing Device

**DESCRIPTION:**

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**SUBMIT REPORT**

**No devices currently defined. You must define at least one device before you can submit the report to the FDA.**

[\[close window\]](#)

## Save Options

Edit Report Save Continue

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**SUBMIT REPORT**

**Report was submitted to FDA successfully**

[\[close window\]](#)

Edit Report Save Continue Ready To Submit

US

Facil

facilit

**SAVE REPORT**

Report **0333020000-2017-8012** was saved successfully

The report is marked to '**Completed/ready to submit**', but it has not been submitted to the FDA yet.

Please notify the reviewer at your facility that the report is ready for review and submission to the FDA.

[\[close window\]](#)

Other

**SAVE REPORT**

Report **0333020000-2017-8011** was saved successfully

What would you like to do?

- [Edit the report you just saved](#)
- [View the report you just saved](#)
- [Go back to the BROWSE screen](#)
- [Print 3500A](#)
- [Print Summary Report](#)

**SAVE REPORT**

Report **0333020000-2017-8012** was saved successfully

The report is marked to 'Completed/ready to submit', but it has not been submitted to the FDA yet.

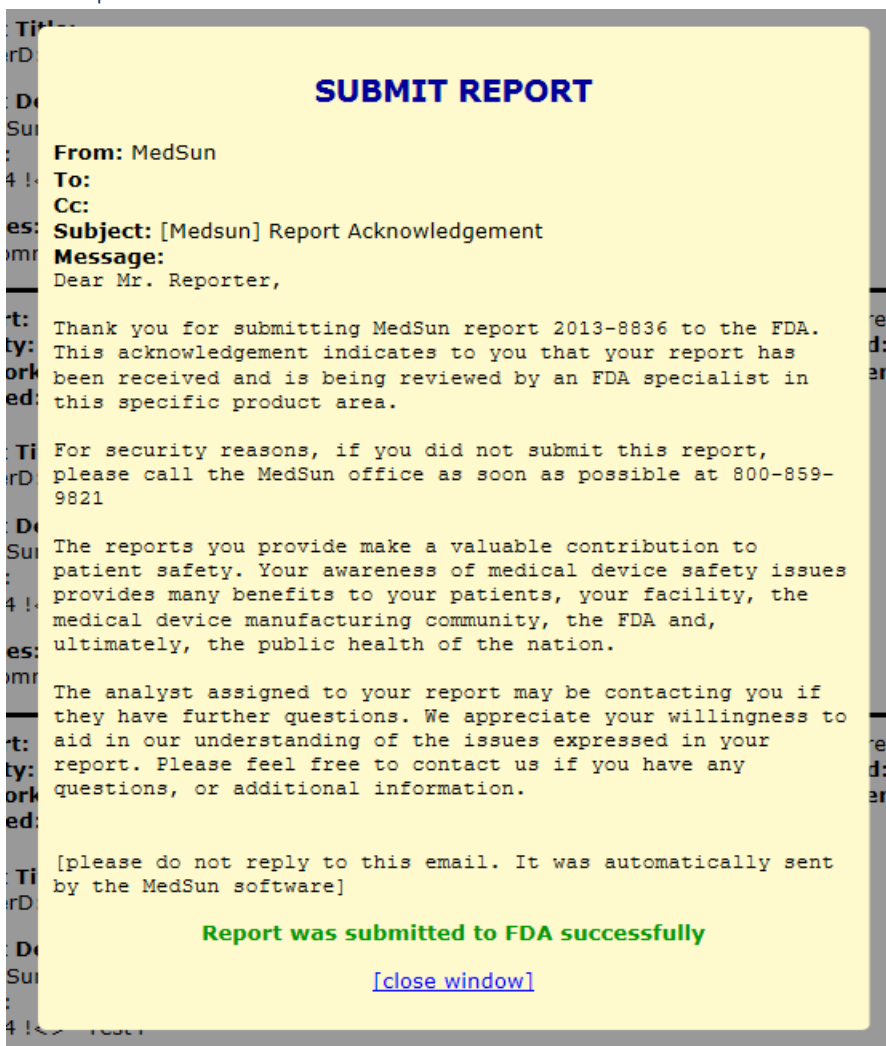
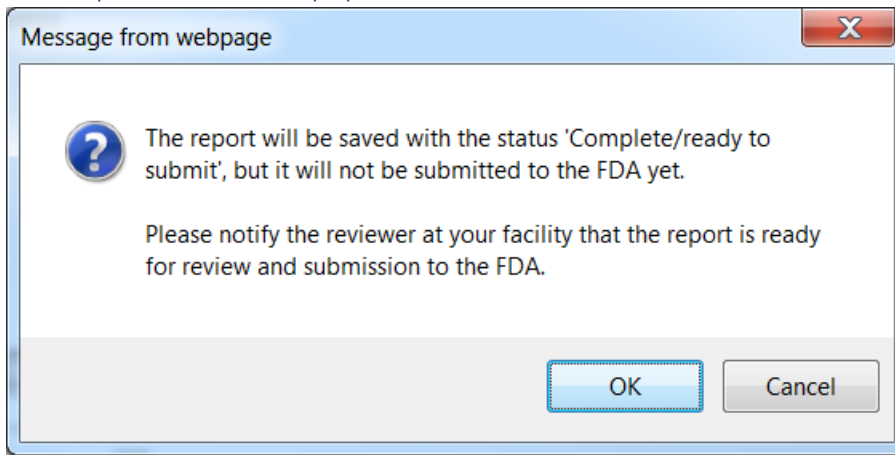
Please notify the reviewer at your facility that the report is ready for review and submission to the FDA.

What would you like to do?

- [Edit the report you just saved](#)
- [View the report you just saved](#)
- [Go back to the BROWSE screen](#)
- [Print 3500A](#)
- [Print Summary Report](#)

The device(s) may have caused or contributed to: (Check all that apply





# Test

Add Report Test List Empty



**Create New Report**  
Test Hospital



[Contact Info](#) [Event](#) [Patient](#) [Device](#) [Test](#) [Attachment](#)

**USER FACILITY**

[Save & Continue](#)


[Save & Exit](#)

[Cancel](#)


## TEST LIST

Enter new Test information...

Add Report Test List



0333020000-2017-8011  
Test Hospital



[Contact Info](#) [Event](#) [Patient](#) [Device](#) [Test](#) [Attachment](#)

**USER FACILITY**

[Save & Continue](#)

[Save & Exit](#)

[Submit To FDA](#)

[Cancel](#)

[Set Report Status](#)

## TEST LIST

Enter new Test information...

[Modify](#) [Remove](#) **Test 1**



### TEST INFORMATION

Test performed:

Date test was performed/administered: (mm/dd/yyyy)

Test results: [limit: 50 lines of text]

### Attachment

Edit/Add Report "Attachment List" Empty



Contact Info Event Patient Device Test Attachment

#### USER FACILITY

Save & Continue

Save & Exit

Cancel

### ATTACHMENT LIST

**You must save new reports before you can upload any documents.**

**MedSun** Medical Product Safety Network **0333020000-2017-8011** Test Hospital **FDA U.S. FOOD & DRUG ADMINISTRATION**

Contact Info Event Patient Device Test Attachment

**USER FACILITY**

Save & Continue  
Save & Exit  
Submit To FDA  
Cancel  
Set Report Status

### ATTACHMENT LIST

Select document to upload:  Browse...  
\* document size must be less than 5MB (5120KB)

---

**No Document found for this Report.**

**MedSun** Medical Product Safety Network **0333020000-2017-8011** Test Hospital **FDA U.S. FOOD & DRUG ADMINISTRATION**

Contact Info Event Patient Device Test Attachment

**USER FACILITY**

Save & Continue  
Save & Exit  
Submit To FDA  
Cancel  
Set Report Status


### ATTACHMENT LIST

Select document to upload:  Browse...  
\* document size must be less than 5MB (5120KB)

---

**1fb5b838096d487b8b78626edf29e15f.jpg has been successfully uploaded.**

---



[view](#) [delete](#)



## MEDSUN ANALYSIS TOOL

### Select the report you want to run:

#### 1. [Report counts per Facility](#)

**Use this report to determine how many reports have been submitted for each facility you manage.**

The summary report will provide the list of facilities, the number of reports for each facility, and the number of devices reported for each facility. The detailed report will also provide the devices that were reported for each facility.

*Why might you want to run this report?*

- You want to know how many reports were submitted by each facility
- You want to know the devices that were reported for each facility

#### 2. [Report counts per Event Type](#)

**Use this report to determine how many reports have been submitted for each event type (e.g. "death", "serious injury", "potential for patient harm", etc)**

The summary report will provide the event type, the number of reports for each event type, and the number of devices reported for each event type. The detailed report will also provide the reporting facility, the devices that were reported for each event type.

*Why might you want to run this report?*

- You want to know how many reports were submitted for each event type (e.g. "death", "serious injury", etc)
- You want to know the devices and facilities that had reports for each event type (e.g. "death", "serious injury", etc)

#### 3. [Report counts per Device Type](#)


**Use this report to determine how many reports have been submitted for each type of device**


The summary report will provide the device (device type and manufacturer), the number of reports for each device and the total number of times that device was listed in the reports. The detailed report will also provide the reporting facility, and the event types (e.g. "death", "serious injury", etc).

*Why might you want to run this report?*

- You want to know how many reports were submitted for each type of device
- You want to know which facilities reported each device and how many times the device was reported for a given facility
- You want to know which event types ("death", "serious injury", etc) were reported for each type of device at each of your facilities

**Select the date range for the report:**

**Start Date**   --OR-- **Quick Pick**

**End Date**  

**Please indicate how you want to view the results:** ▼**NOTES**


**Use this report to determine how many reports have been created for each facility you manage.**


The summary report will provide the list of facilities, the number of reports for each facility, and the number of devices reported for each facility. The detailed report will also provide the devices that were reported for each facility.

*Why might you want to run this report?*

- You want to know how many reports were created by each facility
- You want to know the devices that were reported for each facility

**Select the date range for the report:**

**Start Date**   --OR-- **Quick Pick**

**End Date**  

**Please indicate how you want to view the results:** ▼**NOTES**

**Use this report to determine how many reports have been created for each event type (e.g. "death", "serious injury", "potential for patient harm", etc)**

The summary report will provide the event type, the number of reports for each event type, and the number of devices reported for each event type. The detailed report will also provide the reporting facility, the devices that were reported for each event type.

*Why might you want to run this report?*

- You want to know how many reports were created for each event type (e.g. "death", "serious injury", etc)
- You want to know the devices and facilities that had reports for each event type (e.g. "death", "serious injury", etc)



## REPORT COUNTS BY EVENT TYPE

10/9/2013 to 10/23/2017 ([change](#))

[Download Summary to Excel](#)

[Download Data to Excel](#)

[Go Back to MedSun Analysis Reports](#)


[Printer Friendly](#)


[Show Detail View](#)

Event Type	Report Count (click to view)	Device Count
Death	<a href="#">141</a>	152
Serious injury	<a href="#">445</a>	562
Potential harm to a health care provider [Indicates voluntary report]	<a href="#">5</a>	5
Minor injury to the patient or health care provider [Indicates voluntary report]	<a href="#">40</a>	40
Potential for patient harm [Indicates voluntary report]	<a href="#">288</a>	391
Not known	<a href="#">1</a>	1
Not applicable	<a href="#">2</a>	2
test	<a href="#">2</a>	0
(not answered)	<a href="#">82</a>	73
-- (end of report) --		



**Select the date range for the report:**

**Start Date**   --OR-- **Quick Pick**

**End Date**  

**Please indicate how you want to view the results:****NOTES****Use this report to determine how many reports have been created for each type of device**

The summary report will provide the device (device type and manufacturer), the number of reports for each device and the total number of times that device was listed in the reports. The detailed report will also provide the reporting facility, and the event types (e.g. "death", "serious injury", etc).

*Why might you want to run this report?*

- You want to know how many reports were created for each type of device
- You want to know which facilities reported each device and how many times the device was reported for a given facility
- You want to know which event types ("death", "serious injury", etc) were reported for each type of device at each of your facilities



### Message Topics for Mr. Reporter

[» Post a new topic](#)

(254) record(s) found.

Page 1 of 26

Go To Page: First << < (1) 2 3 4 5 6 7 8 9 10 11 12 13 14 15 > >> Last

Action	Topic
<a href="#">View Messages</a>	<p><b>[Medsun] Report Acknowledgement</b>            Message for Report <b>111110000-2008-8003</b> (<a href="#">view report</a>)            Created by MedSun System (MedSun)            Last Message Date: 9/8/2017 2:48:05 PM  <b>(0)</b> unread messages, <b>(9)</b> total messages  <i>* Messages need your response</i></p>
<a href="#">View Messages</a>	<p><b>Test New Delete SP</b>            Message for Report <b>0333020000-2013-8844</b> (<a href="#">view report</a>)            Created by (MedSun)            Last Message Date: 3/31/2017 11:42:36 AM  <b>(2)</b> unread messages, <b>(2)</b> total messages  <i>* (2) UNREAD messages</i>  <i>* Messages need your response</i></p>



## New Message Topic

[»Back to Topic List](#)

Report

Topic

### Message Body

## New Message Topic Pick Report

### Pick a Report

Find:

(2306) record(s) found.

Page 1 of 116

Go To Page: First << < (1) 2 3 4 5 6 7 8 9 10 11 12 13 14 15 > >> Last

[3600510000-2016-8001](#)

**Submitted on:** 7/8/2016 10:40:27 AM

**Title:** eMDR Test 10/03/2016

**Description**

[Pick](#)

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Etiam volutpat ante a metus hendrerit tincidunt. Cras vitae finibus felis, non ultricies lectus. Nullam scelerisque porttitor blandit. Mauris vitae nunc eleifend, sodales metus eu, luctus enim. Aenean dolor nunc, venenatis ut ante in, ullamcorper tempus lorem. Duis congue justo quis leo malesuada, vel sagittis risus pharetra. Phasellus ornare et libero ac aliquet. Donec non gravida urna. Nullam tristique auctor nibh, in accumsan libero ...



## New Message Topic

[»Back to Topic List](#)

Report

Topic

### Message Body

The software upgrade should be 10.5 not 9.5

Thank you,

MedSun Reporter

## Message New Topic Post

**Your topic was saved successfully.**

What would you like to do?

- [View the topic you just saved](#)
- [View all your topics](#)



## View Messages

[View all topics for report »](#)

[Add a reply »](#)

**Last Message Date:** 01/06/  
(0) unread messages, (1) total messages

test

**Created by:**  
**Created On:**  
**Report:** 0503510000-2010-8010 ([view report](#))

[Mark all as read](#)

## Messages



**W M**  
Test Hospital

**Message #:** 20  
1/6/20 3:01:38 PM

[Mark as unread](#)

[Add a reply](#)


Add your reply in the box below. When you are done, please click the [**Post Message**] button located at the bottom of the page.

## Password




## OPTIONS

[Click here to change your password](#)



Change your password



Home Browse/Edit Add Report Analysis Messages Options BioMed Resources
Logout

Old password\*


Password\*

Retype password\*


**Password must meet the following criteria:**

- at least eight characters
- at least one uppercase letters
- at least one lowercase letters
- at least one numbers (0-9)
- at least one special characters (!, @, #)
- no contextual information (login credentials, email, website, name)

BioMed



Biomed



Home Browse/Edit Add Report Analysis Messages Options BioMed Resources
Logout

Select a Clinic:

Upload Excel file:

**UPLOAD HISTORY**

Clinic Name	Uploaded By	Uploaded On	File Name	Original Count	Min WO Date	Max WO Date	WO Date Overlapped	Status
Testing Site		4/4/2018 1:18:54 PM	<a href="#">FDA_CMMS_U</a>	6	02/22/1999	11/30/2013	Yes	Success
Testing Site		4/4/2018 1:18:17 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Testing Site		4/4/2018 1:15:26 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Testing Site		4/4/2018 1:08:29 PM	<a href="#">FDA_CMMS_U</a>	6	02/22/1999	11/30/2013	Yes	Success
Test Hospital		10/27/2017 4:08:47 PM	<a href="#">FDA_CMMS_U</a>	8	02/22/1999	11/30/2013	No	Success
Test Hospital		10/27/2017 4:05:51 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Test Hospital		10/27/2017 4:05:24 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Test Hospital		3/11/2016 5:03:41 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail



Select a Clinic:   
 Test Hospital  
 Test Report Hospital  
 Testing Site

Filter History

Upload Excel file:

**UPLOAD HISTORY**

Clinic Name	Uploaded By	Uploaded On	File Name	Original Count	Min WO Date	Max WO Date	WO Date Overlapped	Status
Testing Site		4/4/2018 1:18:54 PM	<a href="#">FDA_CMMS_U</a>	6	02/22/1999	11/30/2013	Yes	Success
Testing Site		4/4/2018 1:18:17 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Testing Site		4/4/2018 1:15:26 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Testing Site		4/4/2018 1:08:29 PM	<a href="#">FDA_CMMS_U</a>	6	02/22/1999	11/30/2013	Yes	Success
Test Hospital		10/27/2017 4:08:47 PM	<a href="#">FDA_CMMS_U</a>	8	02/22/1999	11/30/2013	No	Success
Test Hospital		10/27/2017 4:05:51 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Test Hospital		10/27/2017 4:05:24 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Test Hospital		3/11/2016 5:03:41 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail



[Biomed File Upload](#)

<b>Clinic:</b>	Testing Site
<b>File Name:</b>	FDA_CMMS_Upload_TemplateTestingSite4.xlsx
	Uploaded by on 4/25/2019 10:45:49 AM
<b>Original Record Count:</b>	6
<b>Upload Status:</b>	Success
<b>WO Start:</b>	
<b>WO End:</b>	

[Export Results to Excel](#)

**UPLOAD HISTORY DETAILS**

<u>Overlapped</u>	<u>Record ID</u>	<u>Device Type</u>	<u>Manufacturer</u>	<u>Model</u>	<u>Serial Number</u>	<u>UDI</u>	<u>WO Opened Date</u>	<u>WO Type Code</u>	<u>WO Problem Code</u>	<u>WO Problem Description</u>
No	563593	microwave	Ohmeda	6600-0333-901	HCDD00364	UDI1-Col6-Col5	2/22/2018	RPR	PC1	Missing screws
No	563594	Incubator	Ohmeda	6600-0333-901	HCDD00365	UDI2-Col6-Col5	5/1/2018	RPR	PC2	Physical Damage
No	563595	Incubator	GE Medical Systems	PRO 200	010M0119022		11/30/2018	RPR		Monitor does not turn on.
No	563596	Incubator	GE Medical Systems	PRO 400 V1 Nellcor	000M2999067		12/20/2018	RPR		"Broken"
No	563597	dehydrator	TRP	T100000	L100			562390898		Error
No	563598	weighing machine	Airshields	TI1000000	U100		1/1/2018	89997986		Will not run on battery.







The file you are attempting to upload (FDA\_CMMS\_Upload\_Template.xlsx) has column header information that does not match the system's configuration for Testing Site.

For Column A : the expected column header is OTHER5, the actual column header is INFANT0104.

For Column B : the expected column header is MANUFACTURER\_NAME, the actual column header is OHMEDA.

For Column C : the expected column header is MODEL\_NAME\_NBR, the actual column header is 6600-0333-901.

For Column D : the expected column header is SERIAL\_NUMBER, the actual column header is HCDD00364.

For Column E : the expected column header is DATE\_WO\_OPENED, the actual column header is UDI1.

For Column F : the expected column header is UDI, the actual column header is 7/18/2011 3:20:50 PM.

For Column G : the expected column header is WO\_TYPE\_CODE, the actual column header is RPR.

For Column H : the expected column header is WO\_PROBLEM\_CODE, the actual column header is WPO1.

For Column I : the expected column header is WO\_PROBLEM\_DESC, the actual column header is MISSING SCREWS.

For Column J : the expected column header is WO\_REPAIR\_DESC, the actual column header is (TC 7/18/2011, JRS) SCREWS STRIPPED WHEN TECH CHANGED BATTERIES..

For Column K : the expected column header is OTHER1, the actual column header is .

For Column L : the expected column header is OTHER2, the actual column header is XLSX FILE.

For Column M : the expected column header is OTHER3, the actual column header is .

For Column N : the expected column header is OTHER4, the actual column header is .

For Column O : the expected column header is DEVICE\_TYPE, the actual column header is EMILY OTHER5.

Please update the column header information in the Excel file, or email a copy of the file to [MedSun@fda.hhs.gov](mailto:MedSun@fda.hhs.gov) and the FDA administrator will configure your file properly.

Select a Clinic:

Upload Excel file:

**UPLOAD HISTORY**

Clinic Name	Uploaded By	Uploaded On	File Name	Original Count	Min WO Date	Max WO Date	WO Date Overlapped	Status
Testing Site	Jose Estronza	4/25/2019 10:26:25 AM	<a href="#">FDA_CMMS_Uplo</a>	0			No	Fail
Testing Site	Jose Estronza Toro	4/4/2018 1:18:54 PM	<a href="#">FDA_CMMS_Uplo</a>	6	02/22/1999	11/30/2013	Yes	Success
Testing Site	Jose Estronza-Toro	4/4/2018 1:18:17 PM	<a href="#">FDA_CMMS_Uplo</a>	0			No	Fail
Testing Site	Jose Estronza Toro	4/4/2018 1:15:26 PM	<a href="#">FDA_CMMS_Uplo</a>	0			No	Fail
Testing Site	Jose Estronza-Toro	4/4/2018 1:08:29 PM	<a href="#">FDA_CMMS_Uplo</a>	6	02/22/1999	11/30/2013	Yes	Success
Testing Site	Emily Zhou	1/14/2015 10:16:37 AM	<a href="#">FDA_CMMS_Uplo</a>	0			No	Fail
Testing Site	Sudeshna Mandal	6/18/2014 12:21:11 PM	<a href="#">FDA_CMMS_Uplo</a>	8	02/22/1999	11/30/2013	Yes	Success
Testing Site	Sudeshna Mandal	6/18/2014 12:20:57 PM	<a href="#">FDA_CMMS_Uplo</a>	8	02/22/1999	11/30/2013	Yes	Success



[Biomed File Upload](#)

<b>Clinic:</b>	Testing Site
<b>File Name:</b>	FDA_CMMS_Upload_TemplateTestingSite.xls
	<i>Uploaded by</i> 6/18/2014 10:51:57 AM
<b>Original Record Count:</b>	0
<b>Upload Status:</b>	Fail
<b>WO Start:</b>	
<b>WO End:</b>	

### UPLOAD HISTORY DETAILS

#### Error Message

The file you are attempting to upload FDA\_CMMS\_Upload\_TemplateTestingSite.xls has column header information that does not match the system's configuration for Testing Site.

For Column A : the expected column header is OTHER4, the actual column header is OTHER5.

Please update the column header information in the Excel file, or email a copy of the file to [MedSun@fda.hhs.gov](mailto:MedSun@fda.hhs.gov) and the FDA administrator will configure your file properly.



Select a Clinic:

Upload Excel file:

**Uploading file...Please Wait**



NOTE: Please do not hit the BACK button while the system is processing this request.

**UPLOAD HISTORY**

Clinic Name	Uploaded By	Uploaded On	File Name	Original Count	Min WO Date	Max WO Date	WO Date Overlapped	Status
Testing Site		4/4/2018 1:18:54 PM	<a href="#">FDA_CMMS_U</a>	6	02/22/1999	11/30/2013	Yes	Success
Testing Site		4/4/2018 1:18:17 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Testing Site		4/4/2018 1:15:26 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Testing Site		4/4/2018 1:08:29 PM	<a href="#">FDA_CMMS_U</a>	6	02/22/1999	11/30/2013	Yes	Success
Test Hospital		10/27/2017 4:08:47 PM	<a href="#">FDA_CMMS_U</a>	8	02/22/1999	11/30/2013	No	Success
Test Hospital		10/27/2017 4:05:51 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Test Hospital		10/27/2017 4:05:24 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail
Test Hospital		3/11/2016 5:03:41 PM	<a href="#">FDA_CMMS_U</a>	0			No	Fail

Import

Import



**IMPORT REPORTS TO MEDSUN**

This tool will allow you to import reports into the MedSun system. The reports MUST be in XML format.

**\*XML file to import:**

No file selected.



**MedSun Manual**

[MedSun User's Manual](#)

[MedSun Quick Reference - How to submit a report](#)

**MedSun Educational Presentations and Videos**

MedSun Presentations			
Name	Presentation	Handout	Instructor Guide and Script
General Clinical Staff			
Home Health Care			
Laboratory Staff			
Operating Room Staff			
Pediatric Staff			

**MedSun Videos**

**MedSun Outreach:** [YouTube](#)

The Medical Product Safety Network (MedSun) is an adverse event reporting program launched in 2002 by the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH). The primary goal for MedSun is to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices.

**Recognize, Remove, Report Video:** [YouTube](#) [MPEG](#) [Windows Media](#)

The 9-minute Recognize, Remove, Report video illustrates why it is so important for healthcare providers to recognize when medical device problems occur.

**Pediatric Webcast:** [video](#) [Transcript](#)

**MedSun Educational Materials**

[Order Form for FREE Educational Materials](#)

**MedSun Posters**

Poster	Name
1	<a href="#">Recognize, Remove &amp; Report Problems with Medical Devices</a>
2	<a href="#">Broken. Frayed. Cracked. Loose.</a>
3	<a href="#">If you don't say something, who will?</a>
4	<a href="#">Uh-Oh! Don't tape it, remove it!</a>
5	<a href="#">One Misconnection is One Too Many</a>
6	<a href="#">Tiny Hole: Huge Problem</a>
7	<a href="#">If you don't report it, who will?</a>
8	<a href="#">Documenting an Incident or Problem with a Medical Device - Blue</a>
9	<a href="#">Documenting an Incident or Problem with a Medical Device - Green</a>
10	<a href="#">Pediatric Poster - If you don't report it, who will?</a>
	<a href="#">MedSun Poster Series</a>

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