- 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

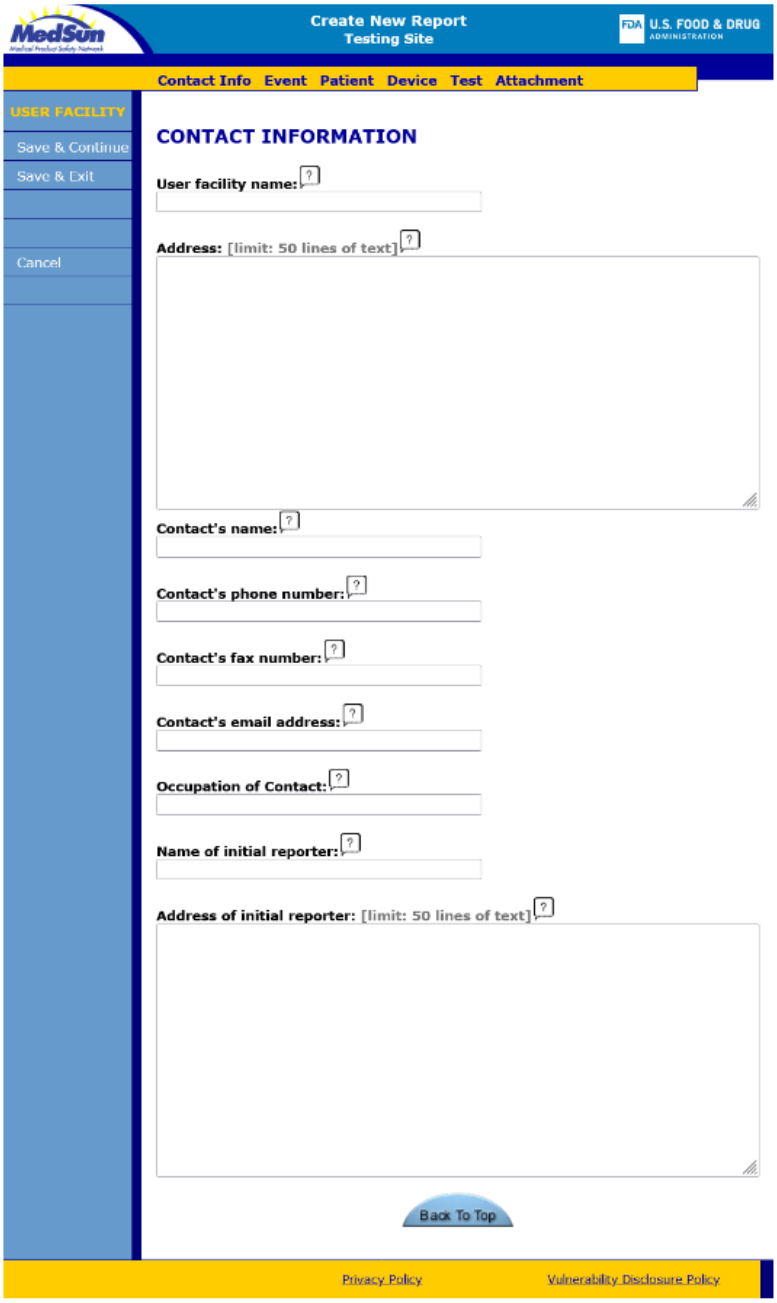
  Public reporting burden for this collection of information is estimated to average 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments 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.

- **FDA FORM 3670 (06/20)**
  OMB Number: 0910-0471
  Expiration date: 07/31/2023

Enter the report form


MedSun
Create New Report
Testing Site
U.S. FOOD & DRUG ADMINISTRATION
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]
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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 20 characters)

Device catalog (REF) #:
(Please limit your response to 20 characters)

Other device #:

Expiration date: (mm/dd/yyyy)

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

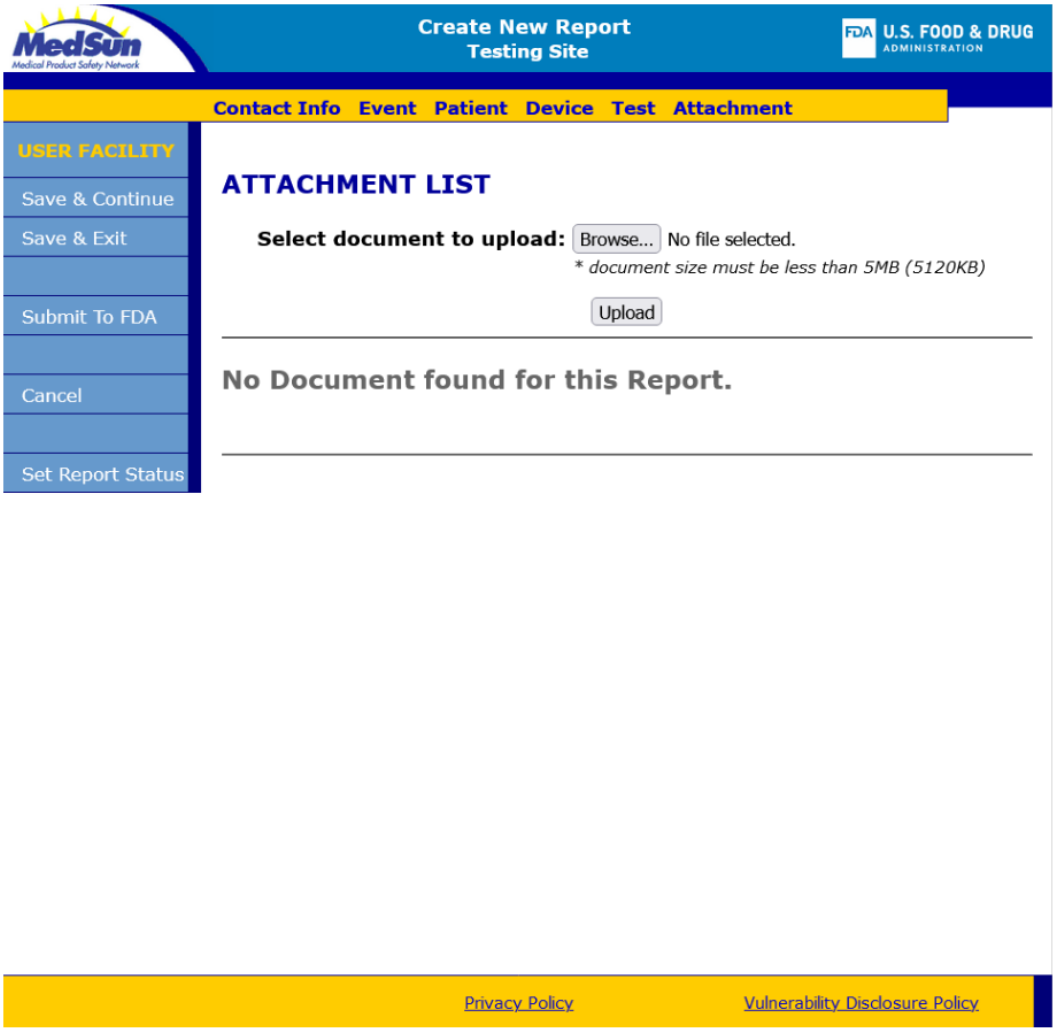
If the device was explanted, give explant date: (mm/dd/yyyy)

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

Cancel Save >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Testing Site
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... No file selected.
* document size must be less than 5MB (5120KB)
Upload
No Document found for this Report.
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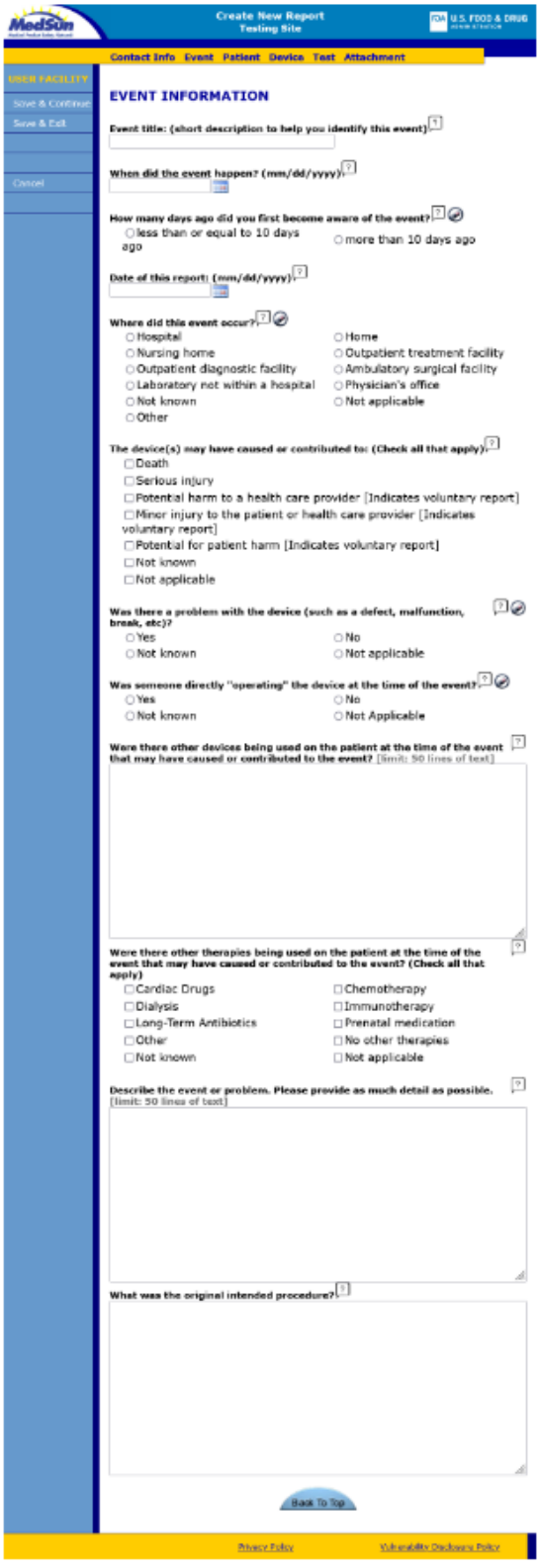
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Contact Info Event Patient Device Test Attachment
USER FACILITY
Save & Continue
Save & Exit
Cancel
EVENT INFORMATION
Event title: (short description to help you identify this event)
When did the event happen? (mm/dd/yyyy)
How many days ago did you 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
Home
Nursing home
Outpatient treatment facility
Outpatient diagnostic facility
Ambulatory surgical facility
Laboratory not within a hospital
Physician's office
Not known
Not applicable
Other
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
No
Not known
Not applicable
Was someone directly "operating" the device at the time of the event?
Yes
No
Not known
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
Chemotherapy
Dialysis
Immunotherapy
Long-Term Antibiotics
Prenatal medication
Other
No other therapies
Not known
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?
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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

Patient's gender:

- ○ Male
- ○ Female
- ○ Not known
- ○ Not applicable

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

Kilograms

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

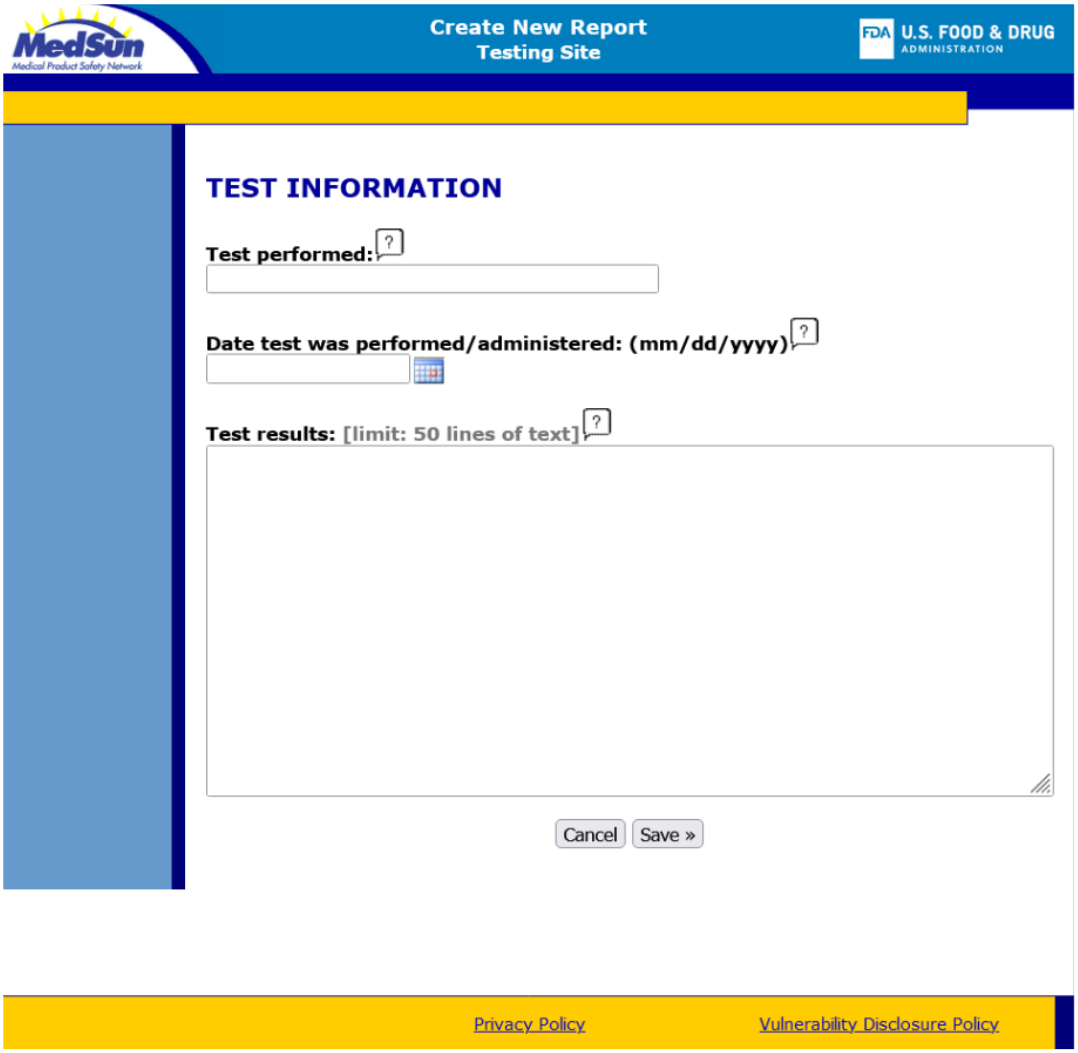
- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ Black or African American
- ☐ Hispanic or Latino
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Unknown
- ☐ Not applicable

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 »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FDA U.S. FOOD & DRUG ADMINISTRATION
TEST INFORMATION
Test performed:
Date test was performed/administered: (mm/dd/yyyy)
Test results: [limit: 50 lines of text]
Cancel
Save »
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