Event ID: _____

Initial Report Date (HERF Q1) _____

Patient Safety Event Report – Hospital:

H DEVICE OR MEDICAL/SURGICAL SUPPLY, INCLUDING HEALTH INFORMATION TECHNOLOGY (HIT)

Use this form to report any patient safety event or unsafe condition involving a defect, failure, or incorrect use of a device, including an HIT device. A device includes an implant, medical equipment, or medical/surgical supply (including disposable product). An HIT device includes hardware or software that is used to electronically create, maintain, analyze, store, or receive information to aid in the diagnosis, cure, mitigation, treatment, or prevention of disease and that is not an integral part of (1) an implantable device or (2) an item of medical equipment.

For defects or events discovered prior to market approval or clinical deployment, do not use this form. If the event also involves a medication or other substance, please complete the Medication or Other Substance form in addition to this form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Which of the following best describes the event or unsafe condition? CHECK ONE:

a. ☐ Device defect or failure, including HIT
b. ☐ Use error
c. ☐ Combination or interaction of device defect or failure and use error
d. ☐ Unknown

2. What type of device was involved in the event or unsafe condition? CHECK ONE:

a. ☐ Implantable device (i.e., device intended to be inserted into, and remain permanently in, tissue)

3. At the time of the event, was the device placed within the patient's tissue? CHECK ONE:

a. ☐ Yes

4. Did the event result in the device being removed? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

b. ☐ No
c. ☐ Unknown

b. ☐ Medical equipment (e.g., walker, hearing aid)
c. ☐ Medical/surgical supply, including disposable product (e.g., incontinence supply)
d. ☐ HIT device

5. What is the name (brand or generic) of the device, product, software, or medical/surgical supply?

_____

6. What is the name of the manufacturer?

_____

7. Which of the following identifiers are known? CHECK ALL THAT APPLY:

a. ☐ Model number
   8. What is the model number? _____
b. ☐ Software version
   9. What is the software version? _____
c. ☐ Firmware version
   10. What is the firmware version? _____
d. ☐ Serial number
   11. What is the serial number? _____
e. ☐ Lot or batch number
   12. What is the lot or batch number? _____
f. ☐ Other unique product identifier
   13. What is the type of other unique product identifier? _____
   14. What is the other unique product identifier? _____
g. ☐ Date of expiration
   15. What is the expiration date? __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
h. ☐ Unique Device Identifier
   16. What is the Unique Device Identifier (UDI)? _____
i. ☐ Asset tag
   17. What is the asset tag number? _____
j. ☐ No identifiers known

18. Was a device intended for single use involved in the event or unsafe condition (including use of a reprocessed single-use device)? CHECK ONE:

a. ☐ Yes
   19. Was a device intended for a single use reused in the event or unsafe condition? CHECK ONE:
   a. ☐ Yes
   b. ☐ No
   c. ☐ Unknown
b. ☐ No
c. ☐ Unknown

20. Did the event or unsafe condition involve a medication or other substance? CHECK ONE:

a. ☐ Yes → **ALSO COMPLETE THE MEDICATION OR OTHER SUBSTANCE FORM**

b. ☐ No

c. ☐ Unknown

IF THE EVENT OR UNSAFE CONDITION DID NOT INVOLVE AN HIT DEVICE — STOP — This form is complete.

IF THE EVENT OR UNSAFE CONDITION INVOLVED AN HIT DEVICE, ANSWER QUESTIONS 21-26

21. Which of the following best characterizes the type of HIT device related to the event or unsafe condition?
CHECK ONE:

a. ☐ Administrative/billing or practice management system

b. ☐ Automated dispensing system

c. ☐ Electronic health record (EHR) or component of EHR

d. ☐ Human interface device (e.g., keyboard, mouse, touchscreen, speech recognition system, monitor/display, printer)

e. ☐ Laboratory information system (LIS), including microbiology and pathology systems

f. ☐ Radiology/diagnostic imaging system, including picture archiving and communications system (PACS)

g. ☐ Other: **PLEASE SPECIFY**

_____

22. Which component of the administrative/billing system?
CHECK ONE:

a. ☐ Master patient index

b. ☐ Registration/appointment scheduling system

c. ☐ Coding/billing system

d. ☐ Unknown

e. ☐ Other: **PLEASE SPECIFY**

_____

23. Which type or component of the EHR? CHECK ONE:

a. ☐ Computerized provider order entry (CPOE) system

b. ☐ Pharmacy system

c. ☐ Electronic medication administration record (e-MAR)

d. ☐ Clinical documentation system (e.g., progress notes)

e. ☐ Clinical decision support (CDS) system

f. ☐ Unknown

g. ☐ Other: **PLEASE SPECIFY**

_____

24. Which of the following describes the circumstances involving the HIT device in the event or unsafe condition?
CHECK ALL THAT APPLY:

a. ☐ Incompatibility between devices
b. ☐ Equipment/device function
c. ☐ Equipment/device maintenance
d. ☐ Hardware failure or problem
e. ☐ Network failure or problem
f. ☐ Ergonomics, including human/device interface issue
g. ☐ Security, virus, or other malware issue
h. ☐ Unexpected software design issue
i. ☐ Unknown
j. ☐ Other: **PLEASE SPECIFY**

_____

25. Which problem(s) resulted from the equipment/device function problem? CHECK ALL THAT APPLY:

a. ☐ Loss or delay of data
b. ☐ System returns or stores data that does not match patient
c. ☐ Image measurement/corruption issue
d. ☐ Image orientation incorrect
e. ☐ Incorrect test results
f. ☐ Incorrect software programming calculation
g. ☐ Incorrect or inappropriate alert
h. ☐ Other: **PLEASE SPECIFY**

_____

26. Which ergonomics or human/device interface issue(s)?
CHECK ALL THAT APPLY:

a. ☐ Hardware location (e.g., awkward placement for use)
b. ☐ Data entry or selection (e.g., entry or selection of wrong patient, wrong provider, wrong drug, wrong dose)
c. ☐ Information display or interpretation (e.g., font size, color of font, location of information in display screen)
d. ☐ Alert fatigue/alarm fatigue
e. ☐ Other: **PLEASE SPECIFY**

_____

Thank you for completing these questions.

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Public reporting burden for the collection of information is estimated to average 10 minutes per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer, Attention: PRA, Paperwork Reduction Project (0935-0143), AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850.