CERNER CORP. CERNER MILLENIUM POWERORDERS SOFTWARE

Model Number 2007.12
Event Date 12/11/2008
Event Type Malfunction  Patient Outcome  Other;
Manufacturer Narrative

Cerner distributed a priority review flash notification in early 2009 to all potentially impacted client sites. The software notification includes a description of the issue and interim workflow adjustment to prevent the malfunction. A software is being developed to address the issue for all the sites that could be potentially impacted. Cerner corporation will provide a follow-up report when the software modification is available.

Event Description

This issue involves the suexecp erx functionality in powerorders and affects users that utilize powerorders electronic routing to document prescription medication orders. When an update is made to the frequency field on an existing prescription, the frequency schedule id is not simultaneously updated on new orders sent to the pharmacy via suexecpents. A patient could potentially take a medication too frequently or infrequently if the pharmacy receives an electronic prescription with the wrong frequency. Cerner received notification that two patients received more than the prescribed dosage of medication as a result of this issue. The first, an elderly patient, was reported to have received more than the prescribed dose of a blood thinner levoxyl for 6 weeks. No serious injury or death has been reported to cerner in association with this issue. A second patient event was reported where the patient received inappropriate dosage orders for carbamazepine and was subsequently admitted to the hospital with atypical chest pains. The client subsequently reported the patient took the correct dosage based on previous instructions and did not rely on the inappropriate dosage as indicated in the suexecpents prescription message.

Search Alerts/Recalls
<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name</td>
<td>CERNER MILLENIUM POWERORDERS</td>
</tr>
<tr>
<td>Type of Device</td>
<td>SOFTWARE</td>
</tr>
<tr>
<td>Manufacturer (Section D)</td>
<td>CERNER CORP.</td>
</tr>
<tr>
<td></td>
<td>2800 Rockcreek Pkwy.</td>
</tr>
<tr>
<td></td>
<td>Kansas City MO 64117</td>
</tr>
<tr>
<td></td>
<td>Shelley Looby</td>
</tr>
<tr>
<td></td>
<td>2800 Rockcreek Pkwy.</td>
</tr>
<tr>
<td></td>
<td>Kansas City, MO 64117</td>
</tr>
<tr>
<td></td>
<td>(816) 201-1368</td>
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<td>Manufacturer Contact</td>
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<td>Device Event Key</td>
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<td>1297453</td>
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<td>Report Source</td>
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<tr>
<td>Source Type</td>
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<tr>
<td>Reporter Occupation</td>
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<td>Remedial Action</td>
<td>Modification/Adjustment</td>
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<tr>
<td>Type of Report</td>
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<tr>
<td>Report Date</td>
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1 Device Was Involved in the Event
1 Patient Was Involved in the Event

Date FDA Received 01/09/2009

Is This An Adverse Event Report? Yes
Is This A Product Problem Report? Yes

Device Operator Health Professional

Device MODEL Number 2007.12

Was Device Available For Evaluation? No
Is The Reporter A Health Professional? Yes
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>Was The Report Sent To Manufacturer?</td>
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<tr>
<td>Date Manufacturer Received</td>
<td>12/11/2008</td>
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<tr>
<td>Was Device Evaluated By Manufacturer?</td>
<td>Yes</td>
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<tr>
<td>Date Device Manufactured</td>
<td>11/01/2007</td>
</tr>
<tr>
<td>Is The Device Single Use?</td>
<td>No</td>
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<tr>
<td>Is this a Reprocessed and Reused Single-Use Device?</td>
<td>No</td>
</tr>
<tr>
<td>Is the Device an Implant?</td>
<td>No</td>
</tr>
<tr>
<td>Is this an Explanted Device?</td>
<td>No</td>
</tr>
<tr>
<td>Type of Device Usage</td>
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</tbody>
</table>

CERNER CORPORATION MILLENIUM ELECTRONIC MEDICAL RECORD

Model Number MILLENIUM
Event Date 12/11/2008
Event Type No Answer Provided
Event Description

Nurses are currently manually entering vital signs data into the electronic medical record (emr). Nurses have noticed that the mean pressure value that is calculated by the emr is sometimes different from the mean value displayed on the patient monitor. A few sample values were obtained: (systolic/diastolic mean) 129/85 81 emr mean 86; 146/78 95 emr 101; 134/54 81 emr 84; 150/98 116 emr 115. We were unable to verify if this occurs with a different patient monitoring vendor (such as in the er) because in that case the emr does not display the mean value. Nurses reporting this problem say that they have seen much larger variations but i do not have specific numbers to report yet. ============= manufacturer response for patient monitor, (brand not provided)==per clinical support with ge, the mean pressure is measured in the oscillometric method and is the most accurate pressure value since the systolic and diastolic are then calculated from the mean. Most emr's take the systolic and diastolic numbers and then calculate the mean using a formula intended for auscultatory readings. Therefore there will be variations.

Event Description

Nurses are currently manually entering vital signs data into the electronic medical record (emr). Nurses have noticed that the mean pressure value that is calculated by the emr is sometimes different from the mean value displayed on the patient monitor. A few sample values were obtained: (systolic/diastolic mean) 129/85 81 emr mean 86; 146/78 95 emr 101; 134/54 81 emr 84; 150/98 116 emr 115. We were unable to verify if this occurs with a different patient monitoring vendor (such as in the er) because in that case the emr does not display the mean value. Nurses reporting this problem say that they have seen much larger variations but i do not have specific numbers to report yet. ============= manufacturer response for patient monitor, (brand not provided)==per clinical support with ge, the mean pressure is measured in the oscillometric method and is the most accurate pressure
value since the systolic and diastolic are then calculated from the mean. Most emr’s take the systolic and diastolic numbers and then calculate the mean using a formula intended for auscultatory readings. Therefore there will be variations.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name       MILLENIUM
Type of Device   ELECTRONIC MEDICAL RECORD
Manufacturer (Section D) CERNER CORPORATION
                    2800 Rockcreek Parkway
                    Kansas City MO 64117
Device Event Key  1349756
MDR Report Key    1288623
Event Key         1228954
Report Number     1288623
Device Sequence Number 1
Product Code      NSX
Report Source     User Facility
Type of Report    Initial
Report Date       12/17/2008

2 Devices WERE involved in the Event: 1 2
1 Patient Was Involved in the Event

Date FDA Received 12/18/2008
Is This An Adverse Event Report? No
Is This A Product Problem Report? No
Device Operator    Invalid Data
Device MODEL Number MILLENIUM
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? No Answer Provided
Was the Report Sent to FDA? Yes
Date Report Sent to FDA  12/18/2008  
Device Age  1 yr  
Event Location  Hospital  
Is the Device an Implant?  No  
Is this an Explanted Device?  No Answer Provided  

Patient TREATMENT DATA  
Date Received: 12/18/2008  Patient Sequence Number: 1  

<table>
<thead>
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<th>#</th>
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<td>2</td>
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</table>
MAUDE Adverse Event Report

CERNER MILLENIUM 2007.9 SOFTWARE: CPOE, EMAR
NONE

Model Number VERSION 2007.9
Event Type Other Patient Outcome Other;
Event Description

Cerner millennium computer system - version 2007.9 - used here at our organization for physician medication orders -cpoe-, nursing documentation, and pharmacy prescription processing has significant deficiencies related to displaying smaller volume values. The deficiency is felt by our organization to be a pt safety concern, which is why the report is being generate. The pt safety issues are detailed below. Issue #1, when the dispensed volumes are assigned by the system, the volumes are rounded to 0.01 mls. This is problematic when new syringes on the market are capable of drawing doses in 0.005 ml increments. Therefore, a dose of desmopressin that was supposed to be 0.025 ml = 0.1 mcg is rounded to 0.03 ml = 0.12 mcg, which represents a 20% error in the dose. This issue is hard coded and not a preference that we can control. This problem has been raised with various individuals at cerner without any resolution. This problem has also been raised by at least 2 other children's hospitals; therefore, our hospital is not alone dealing with this issue. Issue #2, when the volume is less than 0.01 ml, the volume does not display with the order -note: normally it does-. Before pharmacy verification, the order reads as follows "xx mg/n/a ml". This is another safety concern because the nurse trying to administer the dose will have to calculate the volume to be administered. Related to this, we almost had a 10 fold insulin error related to this specific defect. Secondly when the pharmacist tries to verify the order, the order fails in the processing. This issue has also been raised with the cerner corp without a resolution.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name CERNER MILLENIUM 2007.9 SOFTWARE: CPOE, EMAR
Type of Device NONE


Page 1 of 2
Device Event Key 1029855
MDR Report Key 1060683
Event Key 1018749
Report Number MW5007293
Device Sequence Number 1
Product Code LNX
Report Source Voluntary
Reporter Occupation PHARMACIST
Type of Report Initial
Report Date 06/12/2008

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 06/12/2008

Is This An Adverse Event Report? No

Is This A Product Problem Report? Yes

Device Operator Health Professional
Device MODEL Number VERSION 2007.9

Was Device Available For Evaluation? Yes

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Was The Report Sent To Manufacturer? Yes

Is the Device an Implant? No

Is this an Explanted Device?
CERNER CORP. CERNER MILLENNIUM CARENET SOFTWARE

Model Number 2005.02 AND 2007
Event Date 10/15/2007
Event Type Malfunction
Manufacturer Narrative

Cerner has distributed a priority review flash notification October 23, 2007 to all potentially impacted client sites. The software notification includes a description of the issue. While the root cause of this issue remains under investigation, Cerner is blocking the corrupted result type from being written to the database and is displaying a warning message to the end user through a series of change records. In addition, an audit script has been developed and made available to identify orders that possibly are affected by this issue. Cerner corporation will provide an update to you when the root cause of the issue has been determined and a software correction has been made available to all clients.

Event Description

The issue involves functionality in Cerner Millennium Carenet and affects sites that use Inet Interactive View or Powerchart Emar and could affect sites that use Carenet intake and output second generation (i&o2g). When a corrupted result qualifies for the Interactive View, the system might fail to return a full set of results. This occurs if the corrupted result is of a type that is set to be displayed on interactive view. The system displays all results that were processed prior to the corrupted result; however, any results from that point forward are not displayed. When this occurs, the system gives no indication that the result set is incomplete. On the eMar, when the system encounters a corrupted result, the system displays that a rate change occurred for the corrupted result, but not the value to which the rate changed. All other results are displayed correctly. Pt care could be adversely affected, as clinical decisions could be based on incomplete info. There have been no reports of adverse pts events rec'd by Cerner as a result of this issue.

Event Description
The issue involves functionality in cerner millennium carenet and affects sites that use inet interactive view or powerchart emar and could affect sites that use carenet intake and output second generation (i&o2g). When a corrupted result qualifies for the interactive view, the system might fail to return a full set of results. This occurs if the corrupted result is of a type that is set to be displayed on interactive view. The system displays all results that were processed prior to the corrupted result; however, any results from that point forward are not displayed. When this occurs, the system gives no indication that the result set is incomplete. On the emar, when the system encounters a corrupted result, the system displays that a rate change occurred for the corrupted result, but not the value to which the rate changed. All other results are displayed correctly. Pt care could be adversely affected, as clinical decisions could be based on incomplete info. There have been no reports of adverse pts events rec'd by cerner as a result of this issue.

Search Alerts/Recalls

new search  |  submit an adverse event report

Brand Name  CERNER MILLENNIUM CARENET
Type of Device  SOFTWARE
Manufacturer (Section D)  CERNER CORP.
                      2800 Rockcreek Pkwy.
                      Kansas City MO 64117
Manufacturer Contact  Shelley Looby
                      2800 Rockcreek Pkwy.
                      Kansas City, MO 64117
                      (816) 201-1368
Device Event Key  958568
MDR Report Key  935649
Event Key  897723
Report Number  1931259-2007-00006
Device Sequence Number  1
Product Code  LNX
Report Source  Manufacturer
Source Type  Health Professional
Reporter Occupation  Other
Remedial Action  Modification/Adjustment  
Type of Report  Initial  
Report Date  10/29/2007  

1 Device Was Involved in the Event  
1 Patient Was Involved in the Event  

Date FDA Received  10/29/2007  
Is This An Adverse Event Report?  No  
Is This A Product Problem Report?  Yes  

Device Operator  Health Professional  
Device MODEL Number  2005.02 AND 2007  

Was Device Available For Evaluation?  No  
Is The Reporter A Health Professional?  Yes  
Was The Report Sent To Manufacturer?  No  

Date Manufacturer Received  08/31/2007  
Was Device Evaluated By Manufacturer?  Yes  

Date Device Manufactured  05/31/2005  
Is The Device Single Use?  No  

Is this a Reprocessed and Reused Single-Use Device?  No  
Is the Device an Implant?  No  
Is this an Explanted Device?  

Type of Device Usage  Unknown  

Patient TREATMENT DATA  
Date Received: 10/29/2007 Patient Sequence Number: 1  

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</table>
MAUDE Adverse Event Report

CERNER CORP. CERNER MILLENNIUM
POWERCHART/POWERCHART OFFIC POWERCHART AND
POWERCHART OFFICE

Event Date 06/14/2007
Event Type Injury
Manufacturer Narrative

Cerner has distributed a priority review flash notification june 22, 2007 to all potentially impacted client sites. The software notification includes a description of the issue and an interim workflow adjustment to prevent the malfunction. A software modification is being developed and will be available to address the issue for all sites that could be potentially impacted. Cerner corporation will provide an update to you when the software correction has been made available to all clients.

Event Description

The issue involves the message center inbox functionality, used within the powerchart core and powerchart office systems. In the message center inbox, a user can make changes to a new pending message and save the changes without saving the message to a patient chart. If the user then performs the same task on a second pending message, the system replaces the entire text of the second message with the entire text of the first message. Text for the second message is lost. Patient care could be adversely affected, as clinical decisions could be based on incorrect information. This issue can be avoided by users opening all pending messages prior to editing and saving changes to the initial message. This issue will affect only those pending messages that are not open while edits are made to the initial message. Cerner has not been made aware of any adverse patient care events that resulted from this issue.

Search Alerts/Recalls

new search | submit an adverse event report

<table>
<thead>
<tr>
<th><strong>Device Name</strong></th>
<th>POWERCHART/POWERCHART OFFICE</th>
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</thead>
<tbody>
<tr>
<td><strong>Type of Device</strong></td>
<td>POWERCHART AND POWERCHART OFFICE</td>
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</table>
| **Manufacturer (Section D)** | CERNER CORP.  
2800 Rockcreek Pkwy.  
Kansas City MO 64117 |
| **Manufacturer Contact** | Shelley Looby  
2800 Rockcreek Pkwy.  
Kansas City, MO 64117  
(816) 201-1368 |
| **Device Event Key** | 853657 |
| **MDR Report Key** | 871981 |
| **Event Key** | 834536 |
| **Report Number** | 1931259-2007-00002 |
| **Device Sequence Number** | 1 |
| **Product Code** | LNX |
| **Report Source** | Manufacturer |
| **Source Type** | Health Professional |
| **Reporter Occupation** | Other |
| **Remedial Action** | Modification/Adjustment |
| **Type of Report** | Initial |
| **Report Date** | 06/25/2007 |

1 Device Was Involved in the Event  
1 Patient Was Involved in the Event  

Date FDA Received 06/25/2007  

Is This An Adverse Event Report? No  
Is This A Product Problem Report? Yes  

Device Operator Health Professional  

Was Device Available For Evaluation? No  
Is The Reporter A Health Professional? Yes  
Was The Report Sent To Manufacturer? No
**Date Manufacturer Received**: 06/14/2007  
**Was Device Evaluated By Manufacturer?**: Yes  
**Date Device Manufactured**: 10/25/2006  
**Is The Device Single Use?**: No  
**Is this a Reprocessed and Reused Single-Use Device?**: No  
**Is the Device an Implant?**: No  
**Is this an Explanted Device?**  
**Type of Device Usage**: Unknown

**Patient TREATMENT DATA**

Date Received: 06/25/2007  
Patient Sequence Number: 1

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<tr>
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MAUDE Adverse Event Report

CERNER CORP HNA MILLENIUM POWERCHART COMPUTER AND SOFTWARE, MEDICAL

Event Date 10/16/2004
Event Type Injury  Patient Outcome Required Intervention;
Event Description

Nurse entering pt info into him - powerchart. Upon entering height they entered both metric and english measures. When this data comes to pharmacy system the height measures are added together. This then presents false info for pharmacy to use for dose calculations (bsa, ibw, crcl). These could lead to serious or life threatening medication errors. The same summary of height is displayed on flowsheet in powerchart.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name HNA MILLENIUM POWERCHART
Type of Device COMPUTER AND SOFTWARE, MEDICAL
Manufacturer (Section D) CERNER CORP
Kansas City MO *
Device Event Key 548285
MDR Report Key 558593
Event Key 530699
Report Number MW1033654
Device Sequence Number 1
Product Code LNX
Report Source Voluntary
Reporter Occupation  PHARMACIST
Type of Report     Initial
Report Date        10/16/2004
1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received  10/22/2004
Is This An Adverse Event Report? No
Is This A Product Problem Report? Yes
Device Operator     Health Professional
OTHER Device ID Number VERSION 2001.01
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Event Location      Hospital
Was The Report Sent To Manufacturer? Yes
Is this a Reprocessed and Reused Single-Use Device? No
Is the Device an Implant? No
Is this an Explanted Device? No Answer Provided
CERNER CORP. HNA MILLENNIUM POWERFORMS SOFTWARE

Model Number RELEASE 500
Event Date 09/27/2002
Event Type Malfunction
Manufacturer Narrative

Cerner has distributed a software notification to all potentially impacted client sites. The software notification includes a description of the issue and instructs clients to contact hnam powerforms support if they know or think the issue affects them. A software modification is being developed for general release to address the issue for all sites that could be potentially impacted. A supplemental report will be filed when the software modification has been made available to all potentially impacted sites.

Event Description

The issue involves the pvformcontrols. Dll used within the millennium powerforms application. The issue occurs when a user only enters one value into one cell of a multi-alpha / basic grid in the powerforms application. In this scenario, the documented information is not written to the database. This issue could potentially adversely affect patient care if the documentation on a multi-alpha / basic grid was critical to the care of the patient. For example, if the grid were used to document current medications, the lack of a known medication could potentially be a problem for the ordering of other medications. If the grid were used to document current allergies, the lack of a known allergy could potentially be a problem for new medications ordered or other care given to the patient. Cerner has not been made aware of any adverse patient care events that resulted from this issue.

Search Alerts/Recalls

new search | submit an adverse event report
Brand Name: HNA MILLENIUM POWERFORMS
Type of Device: SOFTWARE
Baseline Brand Name: CERNER
Baseline Generic Name: BLOOD BANK SOFTWARE
Baseline Catalogue Number: L-2300 OR PA-20090
Baseline Model Number: RELEASE 500
Other Baseline ID Number: PATHNET BLOOD BANK TRANSFUSION
Baseline Device Family: PATHNET BLOOD BANK
Baseline Device 510(K) Number: K990007
Is Baseline PMA Number Provided? No
Baseline Preamendment? No
Transitional? No
510(K) Exempt? No
Shelf Life(Months): NA
Date First Marketed: 09/01/1990
Manufacturer (Section D): CERNER CORP.
2800 Rockcreek Parkway
Kansas City MO 64117
Manufacturer Contact: Shelley Looby
2800 Rockcreek Pkwy
Kansas City, MO 64117
(816) 201-1368
Device Event Key: 409883
MDR Report Key: 420852
Event Key: 398020
Report Number: 1931259-2002-00010
Device Sequence Number: 1
Product Code: MMH
Report Source: Manufacturer
Source Type: Health Professional
Reporter Occupation: Other
Remedial Action: Notification
Type of Report: Initial  
Report Date: 10/02/2002  

1 Device Was Involved in the Event  
1 Patient Was Involved in the Event  

Date FDA Received: 10/02/2002  
Is This An Adverse Event Report?: No  
Is This A Product Problem Report?: Yes  

Device Operator: Health Professional  
Device MODEL Number: RELEASE 500  

Was Device Available For Evaluation?: No Answer Provided  
Is The Reporter A Health Professional?: Yes  

Was the Report Sent to FDA?: No  
Device Age: na  
Event Location: Not Applicable  

Was Device Evaluated By Manufacturer?: Yes  
Date Device Manufactured: 01/01/2002  
Is The Device Single Use?: No  
Is the Device an Implant?: No  
Is this an Explanted Device?:  

Type of Device Usage: Invalid Data  

Patient TREATMENT DATA  
Date Received: 10/02/2002 Patient Sequence Number: 1  

# Treatment Treatment Date  
1,NA
MAUDE Adverse Event Report

CERNER CORP. CERNER HNA MILLENNIUM COMPUTER SYSTEM

Event Date 07/23/2002
Event Type Injury  Patient Outcome Required Intervention;
Event Description

Rptr was asked to adjust this pt's zosyn dose for renal dysfunction. The most recent serum creatinine reported by lab via the cerner system was 1.5 mg/dl, yielding an estimated crcl about 35 ml/min, so rptr doses zosyn 2.25 gm iv q6h. Today rptr discovered that the pt's scr on 7/23 was actually 3.5 mg/dl, yielding an estimated crcl about 15 ml/min. Therefore the pt's zosyn dose should have been 2.25 gm iv q12h. The pt was at risk for morbidity of this error had not been caught. Rptr spoke with a gentleman from lab, who could not verify where the enormous value had come from. All lab data is tracked electronically by who entered the order, who collected the specimen, who verified the results, etc. This is tracked by the user entering a user name and password upon entering the cerner system. The scr value reported at 1.5 had no tracking data associated with it. It seems to have just appeared on this pt's lab profile, perhaps because of a glitch.

Event Description

Add'l info rec'd from mfr 9/19/03: the hospital's info technology service granted pharmacy employees access to the laboratory's serum creatinine results to add a unit (mg/dl) display. The addition of this unit of measure initially led to a drug dosing inaccuracy. The addition of the units was interpreted as a new serum creatinine result from the laboratory on the event date reported, when in fact, it was result from 14 days earlier. This resulted in two add'l doses of zosyn being administered to an inpatient. The client confirmed the dosing error on september 13, 2002. No add'l pt care issues were reported to cerner. The immediate action taken to resolve the issue was to revoke the pharmacy employees' access to laboratory results. The pharmacy is now granted "read only" access. The database is being corrected to allow only one (1) mg/dl unit value to display within either the pharmacy info system or the laboratory info system. Therefore, the pharmacy will no longer need to add unis to a laboratory results. Cerner has distributed a service flash notification to all potentially impacted client sites. The service flash notifications include a description of the issue.
Search Alerts/Recalls

new search | submit an adverse event report

Brand Name  CERNER HNA MILLENIUM
Type of Device  COMPUTER SYSTEM
Manufacturer (Section D)  CERNER CORP.
2800 Rockcreek Pkwy
Kansas City MO 64117
2551
Device Event Key  397436
MDR Report Key  408446
Event Key  386110
Report Number  MW1025720
Device Sequence Number  1
Product Code  MMH
Report Source  Voluntary
Reporter Occupation  PHARMACIST
Type of Report  Initial, Followup, Followup
Report Date  07/24/2002
1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received  07/30/2002
Is This An Adverse Event Report?  No
Is This A Product Problem Report?  Yes
Device Operator  Health Professional
Was Device Available For Evaluation?  Yes
Is The Reporter A Health Professional?  Yes
Event Location  Hospital
Was The Report Sent To Manufacturer?  Yes
Is this a Reprocessed and Reused Single-Use Device?  No
Is the Device an Implant?  No
Is this an Explanted Device?  No Answer Provided