The FDA’s Medical Device Data System Final Rule defined a medical device data system (MDDS) as "a device" intended to transmit, display, store, or convert (using preset specifications) data from a medical device. Manufacturers of an MDDS "device" are required to register the company and list its MDDS devices with the FDA. The rules also require MDDS devices to be developed and produced using a documented quality management system.

What confused many was whether software could be considered to be an MDDS. This may have been due to the fact that the FDA's definition of a "medical device" did not specifically mention software. However, the draft guidance by the FDA published in 1989 and the Final Rule both make it clear that the FDA intended to, and does regulate software. A bug in software that transmits data from a patient monitor is just as dangerous as a bug in the patient monitor hardware. In fact, the FDA states in its Final Rule that the whole purpose for...
drafting the MDDS Final Rule was to create a category of computer and software devices that could be regulated under a single, lower classification. This also means that companies that don’t comply with these rules could have their products removed from the market.

Iatric Systems has registered with the FDA as an MDDS manufacturer and **listed the appropriate software**. Both the medical device industry and the FDA recognized that there would be difficulties determining whether or not certain devices fall within the definition of an MDDS. As a result, they promised to issue future guidance to help the industry make those determinations clearer. Iatric Systems has taken the added step of requiring that any of its products that could have an impact upon patient safety now must be developed using its documented quality management system, whether they technically fell within the MDDS guidelines or not. So, the next time you need to transmit data from a medical device, like a monitor, ask the vendor if they are complying with the MDDS requirements. Are they using a quality management system to do everything they can to insure that no patients are harmed? We have been since the final rule came out in 2011.

---

**Savings with Barcode Specimen Collection**

Barcode specimen collection virtually eliminates mislabeled specimens. Yet many hospitals ask "how can we afford it?"

Fortunately, this technology quickly pays for itself, as an ADVANCE Healthcare Network article demonstrates:

"One hospital ED reduced turnaround time from 65 minutes to 46 minutes per test, increasing capacity, and netting more than $1 million dollars in annual incremental revenue."

A later issue of ADVANCE then reports these astounding statistics:

- Reducing specimen collection time by 60% and lab receipt time by 100% results in $415,200 in annual productivity savings
- Ending the need for follow-up time correcting labeling errors yields $3,400 in annual productivity improvements
- Eliminating even one lawsuit every four years saves an average of $200,000 in litigation costs and $1 million in settlement costs

**Read our recent article in ADVANCE** for more information.

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**Comprehensive Healthcare IT Integration**

You’ll see how more than 1,000 hospitals are using our data integration, systems integration, and process integration solutions for...

- Medical Device Integration
- HIE Implementation
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LOCATION: Orange County Convention Center
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**Leapfrog**

Eighty-eight hospitals earned The Leapfrog Group’s annual "Top Hospital" designation for 2013. The Top Hospital designation, which Leapfrog describes as the most competitive national hospital quality award in the country, recognizes hospitals that deliver the highest quality care by preventing medical errors, reducing mortality for high-risk procedures like heart bypass surgery, and reducing readmissions for patients being treated for conditions like pneumonia and heart attack. This year’s Top Hospital list includes a record 22 Top Rural Hospitals, 55 Top Urban Hospitals, and 13 Top Children’s Hospitals.

A record number of 1,324 hospitals voluntarily participated in this year’s Leapfrog Hospital Survey. The survey focuses on three critical areas of hospital care: (1) how patients fare, (2) resources used to care for patients, and (3) management practices that promote safety and quality. To qualify for this honor, eligible hospitals must also earn an "A" from Leapfrog’s Hospital Safety Score, which grades hospitals based on expert analysis of infections, injuries, and medical errors.

Iatric Systems recognizes our customers who made this prestigious list.

Visit the Leapfrog site to view the complete list, and our congratulations to all the hospitals that made this list, particularly the more than 40 hospitals receiving the award for the first time.

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**Compliance Corner**

Kay Jackson, Manager, Software Certification, and Compliance

Does your vendor help you with Meaningful Use attestations or audits as well as tracking your numbers on a dashboard?

Since I became a student of Meaningful Use (MU) three years ago, I have read a lot and experienced even more. The best part of my job is helping our customers during attestation, researching a MU question for them, and even helping them when they receive the terrible MU audit email notice. Iatric Systems prides itself on our mission "Our products and services focus on data integration, systems integration, and process integration." But many of our customers tell me it goes even deeper than the integration we offer. Our company’s ability to both assist our customers on MU issues and become part of
the MU journey means that we are there when our customers need us.

**Attestations:** Over the past few months, our MU team has assisted many customers during the attestation process. We have set up WebEx meetings and watched as they undergo the attestation process — from helping with the [Certified Health IT Product List (CHPL)](https://www.hitech.org/chpl), to how to respond as they complete the attestation questions, to just rejoicing with our customers as they hit the submit button when the attestation process is completed. When we receive word that a customer has attested, we pass the message around to our whole MU team and celebrate with the customer, because their attestation success is our success as well. So, if your vendor does not rejoice in your success, give me a call in 2014.

**Questions:** Many times, customers ask MU questions that we may not know the answer to, and we relish the chance to learn more. We share our findings with our customers and allow our customers to arrive at their understanding of the issue based on any research we provide. It really takes a village to be successful with Meaningful Use; our team is ready to provide that assistance when called upon.

**Audits:** Since the first audit emails for attestation year 2012 went out this October, we have also assisted customers in responding to their audit requests. The current audits request five items, and failure to respond within three weeks could result in repayment of your incentive funds. The last thing your facility wants to face is failure of an audit, because you must repay the funds in 60 days or pay interest. Even if you plan to appeal, repayment must occur first.

If you want suggestions on what to retain in the event of any audit (which can occur up to six years from the attestation date) feel free to contact me. My feeling is that you can never retain too much proof, because no one can predict what the audit company may want when your facility is selected for an audit.

**Tracking:** If your hospital struggled with attestation numbers in Stage 1, be prepared, because Stage 2 will be ever more challenging. Adding to those challenges is the fact that four of the 201 Core Measures require tracking multiple sub measures. In addition, the 2014 Meaningful Use Clinical Quality Measures (CQMs) require all providers, regardless of their Stage, to attest to the 2014 CQMs, and the new CQMs add several layers of complexity. So far, the auditors have not asked for proof of any of the 2011 CQMs during an audit, but 2014 CQMs will be a different story.

If you are searching for a certified system solution that can track any HIS system(s) in near real time for your Core and Menu Measure, as well as providing options to select any combination of the 29 certified CQMs for 2014, contact your Iatric Account Manager and take a look at what [Meaningful Use Manager](https://www.iatricsystems.com/products/meaningful-use-manager) Dashboard and CQM can provide. Iatric Systems offers both solutions for Eligible Providers as well.

With the news released on December 6 that [CMS proposes 2-year extension of Meaningful Use Stage 2](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Safety-Quality-Care/Quality-Patient-Safety/Patient-Safety/Downloads/meaningfuluse2yearextension2013.pdf), there will be lots of questions. We are here to help you sort through the maze. Iatric Systems offers many other 2014 certified solutions as well.

For 2014, Iatric Systems is ready to become your partner in MU. Happy holidays to everyone and thank you for allowing our team to be part of your success.

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**Report Writing Tips**

Joe Cocuzzo, Senior Vice President – Report Writing Services
There is a "Sunday Puzzler" feature of Weekend Edition on NPR Radio on Sundays. The host is Will Shortz, crossword editor of the New York Times. Occasionally, he provides a puzzle that can be solved by exploiting MAGIC string operators and the spell check dictionary, or this week, using the Zip code dictionary and a specially rigged MPI.

The **listener challenge from December 8th**; deadline for submission Thursday, December 12th at 3pm ET.

"**Next week's challenge from listener Pete Collins of Ann Arbor, Michigan:** Name a U.S. city in nine letters. Shift the third letter six places later in the alphabet. Then shift the last letter seven places later in the alphabet. The result will be a family name featured in the title of a famous work of fiction. What is the city, and what is the family name?"

We have, in effect, a dictionary of US cities in the MIS.ZIP dictionary and we can check the MRI name index for a last name match to find family names that might solve the puzzle. We will need to cheat a bit on the last count.

First we write an MRI.PAT report using the "actual.name.index" as follows:

We set up the report so that we do an LI selection against a list of last names:

Next, we write a start macro that loops through all the zip codes in MIS.ZIP, picking out all the cities that are nine characters long, and then changing the 3rd and the 9th character as specified and trying to match that new string to any last names in the MPI.

If we get a match, we will build a structure like this:

CITY^/LAST[NEWSTRING]  where NEWSTRING has a 3rd and 9th character changed per the puzzle rules.
Hint: I started the report at a hospital in Oregon that appeared to have a complete Zip code dictionary, but found it lacking and had to move the report to a Michigan hospital to solve the puzzle.

The first part of the macro creates a list of nine character cities in a temporary array:

```
DO(CITY(CITY%9)CITY 1,
  IF(CITY%2)+6+LETTER%91 D(LETTER)%91 CHAR,
  CITY%2_CHAR(CITY%22)%NEWCITY,
  IF(CITY%8)+7+LETTER%91 D(LETTER)%91 CHAR,
  NEWCITY%8_CHAR%NEWCITY,
  NEWCITY%last.name.indexed,
  @First(first.name.indexed, actual.name.index) CITY/LAST(last.name.indexed)))
```

Remember that MAGIC numbers characters in a string starting from zero, so when we need to change the 3rd and 9th characters, we get the characters like this:

- CITY#2 = third character
- CITY#8 = ninth character

Before we change the string, we change it to all upper case like this:

```
@MIS.ZIP.city$L.TO.U^CITY
```

The ~ is the translate operator and the $L.TO.U is a system string for MAGIC hospitals that will allow the translate to change a to A, b to B, and so on.

In C/S you would use the @Trl2u function like this:

```
@MIS.ZIP.city@Trl2u^CITY
```

We are supposed to move six down the alphabet for the third character (A becomes G, for example) and seven down the alphabet for the ninth character.

If we take the E(ncode) value of the third character and add six and then take the D(ecode) of that number, we will move six "down" the alphabet. To avoid going past "Z" we check to make sure we are under 91 in the ASCII table.

We make a new string "NEWCITY" by using the $ and % operators to take everything to the left of the 2nd position $2, concatenating the new third character, then concatenating everything to the right of the 2nd position.

We do the same thing with the 9th character, but adding seven rather than six. Because this is the last character, we can just do NEWCITY$8_CHAR^NEWCITY to make the final change.

```
NEWCITY%last.name.indexed,
```

The final step is to use the new string in the actual name index as the "last.name.indexed" subscript and use the @First() operation to see if there are any patients with that last name in the MPI. You could also use @Next if you did...
it like this:

```
NEWCITY^last.name.indexed
""^first.name.indexed,
IF{(@Next(first.name.indexed,@actual.name.index)
CITY^/LAST[last.name.indexed]}
```

@First loops from nil and does not assign back to the subscript

Looking at the object code for @First vs @Next will illustrate:

Translating Logic: MRI.PAT.zcus.is.weekend.puzzler.M.show
IN: @First(first.name.indexed,@actual.name.index)
OUT: +EAN(M.eaANM,"")
IN: @Next(first.name.indexed,@actual.name.index)
OUT: +EAN(M.eaANM,eaANM)

If we run this report in just the right hospital (with a certain city in the Zip code dictionary) and just the right set of folks in the MPI, we can solve the puzzle:

<table>
<thead>
<tr>
<th>RUN DATE: 12/09/13</th>
<th>Sturgis Hospital »MED RECORDS»</th>
<th>PAGE 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>RUN TIME: 2056</td>
<td>US CITY TO FAMOUS NAME</td>
<td></td>
</tr>
<tr>
<td>RUN USER: MIS.JB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAST NAME</td>
<td>CITY</td>
<td></td>
</tr>
<tr>
<td>KARAMAZOV</td>
<td>KARANAZOD</td>
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</tr>
<tr>
<td>M00000270</td>
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<td>KARAMAZOV, DMITRI FYODOROVICH</td>
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</tr>
<tr>
<td>M00000688</td>
<td>KARAMAZOV, DMITRI FYODOROVICH</td>
<td></td>
</tr>
</tbody>
</table>

You have until Thursday 3pm ET to submit an entry.

I actually gave up on the cities in the Oregon hospital’s zip code dictionary after reviewing all the changed nine character strings manually and finding no likely solutions. Next, I got a list of US cities from some internet crossword puzzle dictionary and ran the string transformation against that list and saw that I’d need to find a customer in Michigan and also register some of just the right brothers in their test MPI to get my puzzle report to work.


Read Joe’s blog posts at MEDI-Talk.

To subscribe for email notifications for new Report Writing classes, please follow this link: http://www.iatric.com/Information/Classes.aspx.

For more information, please contact Karen Roemer at 978.805.3142 or email karen.roemer@iatric.com.
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