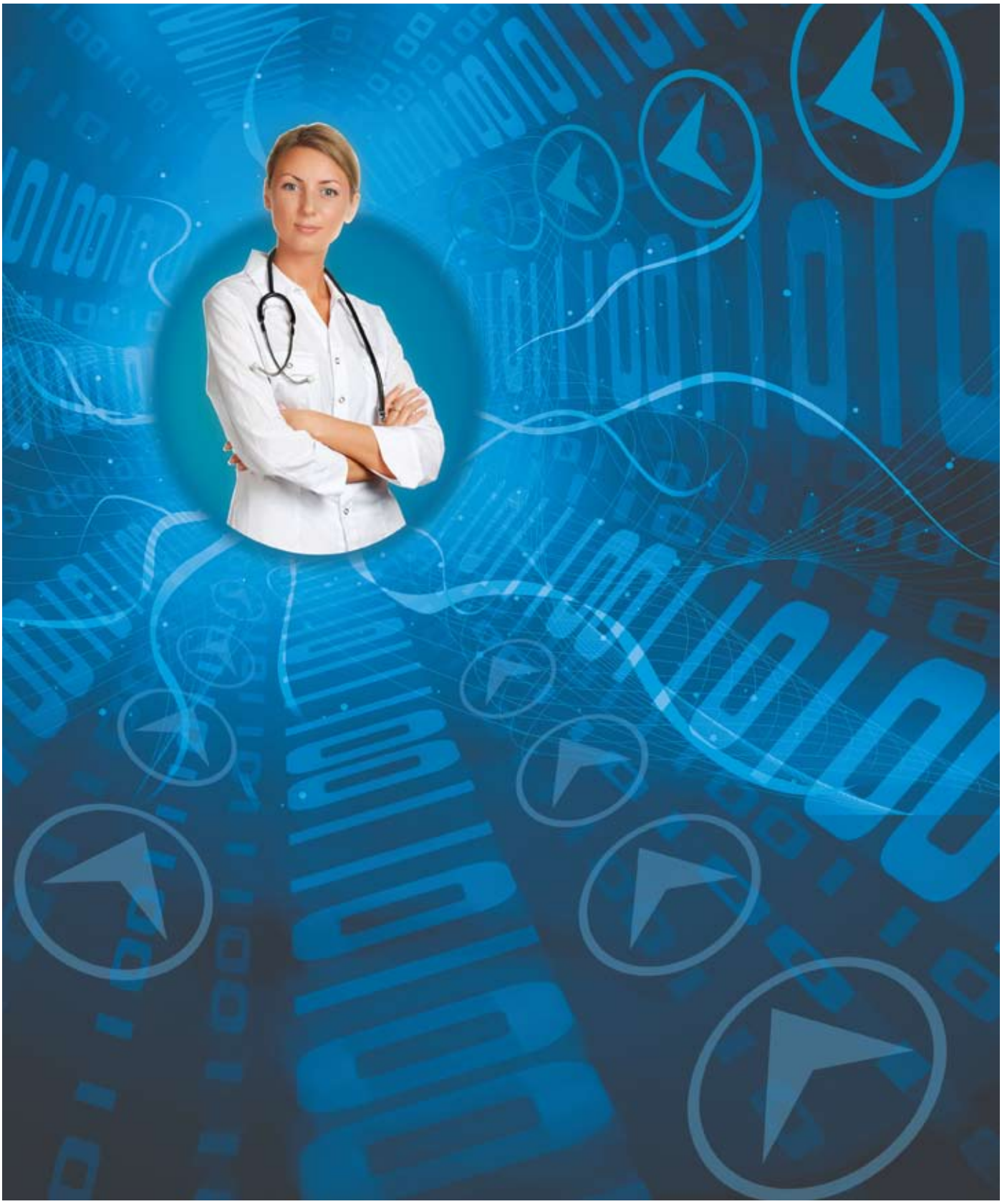
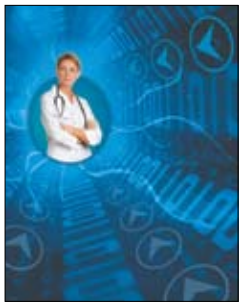
Vol. 11 No. 1

MSP *Industry Alert*™

PROFESSIONAL INFORMATION TRANSFORMING NORTH AMERICAN HEALTHCARE MARKETS™





V11N1 Data Integration

Feature Articles

Industry Alert™ newsletter (V11N1). *Industry Alert™,* published three times a year by Medical Strategic Planning, Inc., 5 Shelbern Dr., Lincroft, NJ 07738-1324. Annual subscriptions are available to hospitals for $95 per year. Printed newsletter delivery subscriptions are offered to others for $495 per year, or to obtain electronic newsletter delivery prices, or to obtain a subscription visit us online at www.medsp.com, call 732-219-5090 or email betty@medsp.com. *Industry Alert™* does not accept advertising. Single copy price is $45 to hospitals and $145 to other US subscribers. International subscribers add $20 per year for additional postage. Periodical postage paid at Lincroft, NJ 07738 and additional mailing offices. Contact MSP for reprint permissions and prices.

MDDS – Key to Clinical Data Integration at the Point-of-Care

Healthcare today is all about three critical goals:

1. Improving clinical decision support;

2. Improving workflow, and;

3. Reducing preventable adverse events.

The third point, reducing adverse events, must include events that are the result of transcription errors, miscalculations or incorrect administration of drugs, failure to positively identify patients, failure to provide critical information in a timely manner at the point of care and failure to deploy the RRT (Rapid Response Team) when a patient's condition is deteriorating. Hospitals that positively address these three related goals will see their costs drop and their bottom line remain in the black. At the end of last year, that was less than half of the hospitals in the U.S.

Hospitals in the past have tried to address these goals in a piecemeal fashion, but have only succeeded with one objective at the expense of making another worse. They no longer have that luxury; today hospitals need to achieve all three intentions simultaneously if they are to remain profitable and viable.

Clinical Data Integration at the Point-of-Care The answer for many hospitals is clinical information integration and management via a Medical Device Data System (MDDS), delivered to the point-of-care to enhance decision support and empower earlier intervention to prevent complications. Doing this well keeps caregivers informed as to what needs to be done, and empowers them to make better decisions about how to do it.

"Data" Routing Challenges But the quandary has been differentiating streaming clinical data (vital signs mostly) from patient alert and alarm information, and routing it all to the appropriate locations.

All patient "data" (including any devices interfaced at the bedside to the bedside monitor) must be continuously processed for the systems that will receive it.

Snapshots and trends of vital signs, and logs of alert/alarm events, must be routed to the hospital's Electronic Medical Record (EMR) system and then forwarded and ultimately integrated into a hospital-wide Electronic Health Record (EHR) or Clinical Information System (CIS) in medical records.

All clinical data must be forwarded to the central station or surveillance center. Alert and alarm data must also be directed to the patient's caregivers, but because both the patient and the caregiver can be mobile, systems available from a specific, clinical device manufacturer will not handle all of the essential connections.

A monitoring system can only connect the patient to the central nursing station, where the mobile nurse generally isn't working. The link for the central station to the mobile nurse is missing – or (if supplied) depends on a secondary, external system such as paging, which isn't tracked by the monitoring system.

This communication and data management problem is growing as the number of devices that contain clinical data are increasing; leading many hospitals to standardize hospital-wide on fewer vendors.

Over the last decade alone (as shown), the number of devices that need to be interfaced has grown from a handful to over 400 major devices available from many different manufacturers whose systems and devices are installed in hospitals.

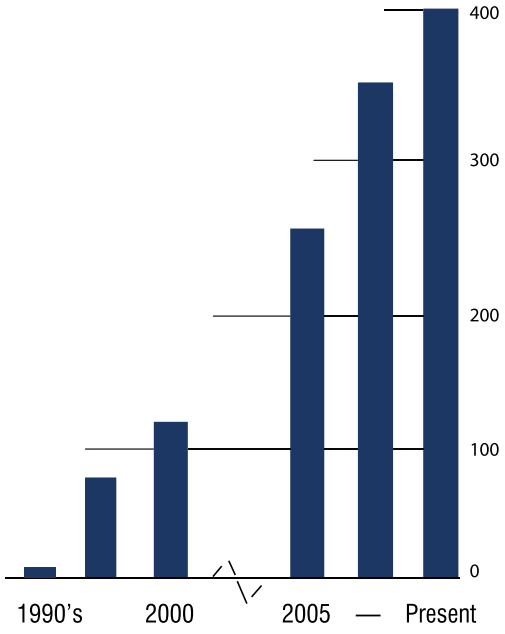
In the early days, in the ICU for example, monitoring system companies tried to integrate data from the bedside and deliver it to the central station or surveillance center.

Data Collection Challenges The first task was to collect and consolidate all the clinical information available on a patient. Considering that a patient may be connected to numerous devices in an ICU – ventilators (or gas machines in the OR), patient monitors, infusion pumps, blanket warmers, bedside blood chemistry devices, urinary catheters, and even chest tubes – this was no small problem.

Increasingly, yesterday's ICU patients are being treated in either step-down or other subacute care settings. Monitoring systems used in these subacute areas are generally wireless and patient-worn devices, or they don't exist at all, as in many general wards today. Yet patients in these areas are connected to IV pumps and may need continuous vital sign monitoring.

Mining Data From the ICU So the first obstacle to solve is how to collect all of the information that needs to be collected, no matter what type of clinical unit the patient is in. There are several alternative solutions to this part of

Number of Devices Requiring Integration is Growing



the problem. In the ICU, patient data is available sent from a patient monitor to the central station and from there through a gateway to the hospital network (and any device that looks for patient data on that network).

The Bedside Monitor as the Point of Integration The approach traditionally promoted by monitoring companies was to interface other monitoring and therapy devices (i.e. ventilators or continuous cardiac output monitors) located around the patient into the patient monitor, using the monitor as a point of consolidation. Indeed, each of the major monitoring vendors created a way of integrating such devices.

Two decades ago, Spacelabs introduced the first bedside module to do this, which created two problems. First, the approach required one module at the bedside per one device to be interfaced. If there were 3 or 4 devices, there were the same number of bedside modules. Bedsides with so many module slots were costly and so were the interface modules themselves – so this approach quickly became prohibitively expensive. Second, it was inherently non-mobile, which while not a problem in the ICU, was a problem everywhere else.

In spite of these problems, competition compelled Hewlett-Packard (now Philips) and Marquette (now GE Healthcare) to quickly follow the Spacelabs approach. Hewlett Packard (HP) introduced VueLink modules for their monitoring system, but hospitals quickly realized that having one module for each type of device that required interfacing was both a non-scalable solution. All of these vendors were dealing with competing market requirements because they were both monitoring (device) companies and they had ICU/OR Clinical Information applications (IT). There was one set of requirements for patient monitoring and another set of different requirements for device integration to CIS. So the approach to device integration changed.

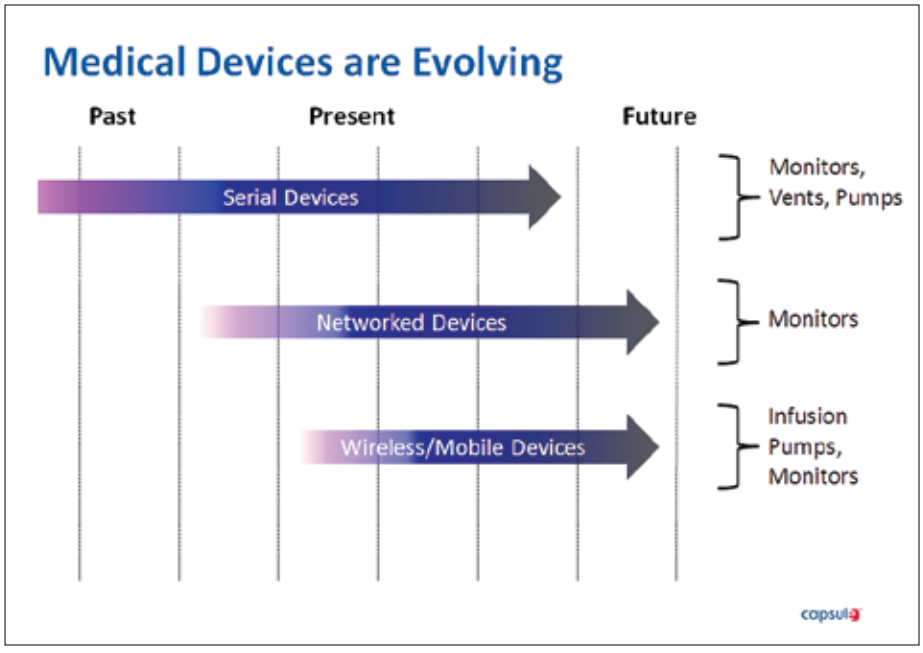
Enter Device Link – The Second Generation Solution Hewlett-Packard (now Philips) introduced Device Link. Device Link supported the integration of up to 8 bedside devices using RS-232 (Medical Information Bus-compatible connectors) that other bedside devices could plug in to. It made the data outputs to its own CareVue (EMR), a clinical information system product.

Device Link originally required its own, separate Ethernet network to connect each bedside device to a centralized, computer-based "traffic cop" controller. Each controller could accept up to 1,000 bedside Device Link interfaces; but this meant running Ethernet cable all over the hospital, which was expensive and disruptive. This hospital-wide cabling was necessary because Device Link didn't originally use the same network for its communication that all of the bedside monitors used to communicate with the central station.

Marquette Octacom Having watched HP, Marquette (now GE Healthcare), had already matched the HP approach, but upped the ante by making the bedside integration device look like a virtual bedside monitor. This allowed it to communicate with the central station over the same IP-based (GE Unity) bedside network that their bedside monitor used. Gone was the need for the second, hospital-wide, secondary Ethernet network and the central controller "traffic cop" that Device Link required. Marquette (GE) actually integrated the information into the bedside monitoring network, without the infrastructure required by HP's Device Link. So, problem solved, right? Well, not really. What about integration in areas where there were no bedside monitors, or for devices that didn't have RS-232, Medical Information Bus (MIB) compatible outputs? And those weren't the only problems.

Who's Responsible for the Interface? Another problem that emerged was the issue of who should write and maintain the drivers that allow the bedside monitor to "talk" to other devices? Who would be responsible for testing these interfaces to be certain that they were robust and safe? What happened when the software in the interfaced device was changed, who was responsible for updating the interface driver – the company that made the device, or the bedside monitoring vendor? When a new driver was (re) written, who was responsible to retest it and make certain that it didn't cause a device or monitor malfunction?

Adoption of EMR Complicates Integration Problem As time passed and electronic charting grew (see time



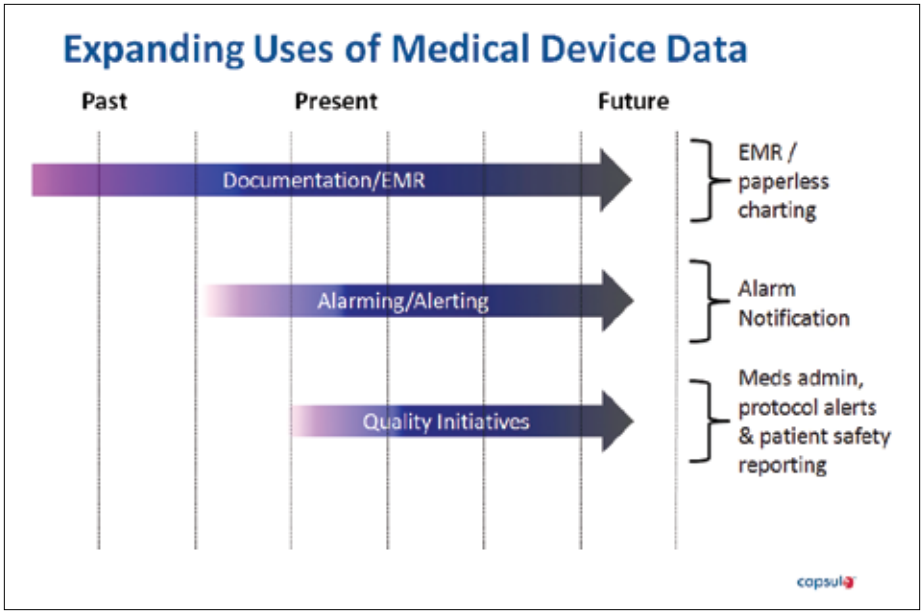
line), the need for all bedside devices to integrate with the bedside EMR (electronic medical record) system became apparent, but who would write all of those interfaces – the monitoring company or the EMR company? How would the EMR get that information from the bedside monitor? EMRs today want to "talk" HL7, but none of the patient monitoring systems natively "talked" HL7.

To address their need to integrate with EMRs, GE Healthcare came out with its Aware Gateway, a bidirectional, HL7 device that supports bidirectional HL7 messaging. It works for the 25% of hospitals that have some GE monitors, but what about other monitoring systems installed in these same accounts? Vendors complained that their competitors weren't all that anxious to provide them with interfaces, or take responsibility for them. This forced hospitals to look for a more universal and scalable solution.

Why Would We Do That? Imagine that you are the marketing manager at an infusion pump or ventilator or bedside blood chemistry company and you want your device's data to be available to the hospital's EMR and any patient monitors located at the bedside (for areas that don't have EMRs deployed). You decide to propose this to your Director of Engineering over lunch. While he is starting on dessert, you make your proposal.

As he chokes on his chocolate brownie, he stammers, "Do you know what you are asking? There are 9 major monitoring systems, all of which have different system protocols – which they aren't anxious to provide to us. Each monitoring system will require a different interface from our devices. Even if we do it, it will cost about $50-200K per interface and we still need each vendor to integrate the data we are sending over on their side from our devices and pass it on to the hospital's EMR vendors.

That isn't simple either. Some EMRs accept streaming data (like a fire hose) in HL7 formats, while others want the data to be buffered and transmitted only when "polled". We decided to do an HL7 interface on our new devices and that has already cost $500K. Before we're done its likely to be a million bucks. We aren't taking on integration with 9 more bedside monitoring companies, all of which have non-standard, proprietary approaches."



The engineering director makes a good point. Should hospitals now have to adopt two different integration approaches, one for GE and one or more for other monitoring vendors installed in the hospital? What about hospitals that standardize on Philips, Nihon Kohden, Draeger, Spacelabs or some other vendor? If they are locked into any monitoring vendor by their data integration strategy, they can't make a switch to a new monitoring vendor unless that company could support all the interfaces required. The hospital would have to switch out the integration components they had already paid for once, just because they were changing monitoring system vendors.

A Marriage Destined for Divorce Unless one sees the cosmos of clinical devices revolving around the bedside monitor, this proposed marriage of monitoring and data integration makes little sense. It prevents the hospital from optimizing the cost of bedside monitors independent of its device data integration approach, and doesn't address at all the integration required in clinical areas where there are only infusion pumps and standalone monitors. It is clear that the approach of having the monitoring company itself act as the data integration vehicle is too expensive, not flexible enough and will limit a hospital's ability to choose best-of-breed solutions. As a result, most hospitals have dismissed this approach as too limiting, monitor-centric and costly.

Separating Data Integration from the Bedside Monitor A better and more adaptable approach is to have a third party handle the data interfacing on an enterprise basis, by deploying one system that can interface to virtually any monitoring system, any brand of ventilator, any type of bedside chemistry device, any infusion pump or other device at the bedside and to all EMRs in all clinical areas.

Capsule Provides the MDDS Required Capsule is a data integration company that takes on the role of collecting and processing the data from all clinical devices and making it available in formats that EMRs and enterprise systems (like Emergin's alarm notification) can accept. For locally connected devices, such as those with RS-232, Capsule does this with a data interface, device-specific serial cable and device

ID module for each device to be interfaced. There can be several devices at each patient location, all interfaced in this manner. The approach is clean and direct because it uses commercially-available cabling to connect to the Capsule DataCaptor terminal server, which then connects to the hospital's enterprise-wide data backbone or Local Area Network (LAN).

The Capsule approach eliminates the rivalry between competing device vendors because interfacing with Capsule is a vendor-neutral affair that is in everyone's best interest. Hospitals can reasonably require all medical device manufacturers to support this one MDDS as a pre-requisite for them to sell their devices to the hospital. It also makes for fewer, more standardized (and therefore less expensive and safer) integrations because it takes data from many input devices and then sends the data on to many EMRs and other output devices; but avoids the problem of having all input devices write drivers for all EMRs and output devices.

Moving to a device-independent approach also serves medical device manufactures by reducing their product development costs. Hospitals find this more attractive also because not only does it reduce overall data integration costs, it also provides them the freedom to choose best-of-breed solutions that are not compounded with data integration problems. It is a safer approach because there are fewer organizations involved in moving data from the point of care to the appropriate caregiver.

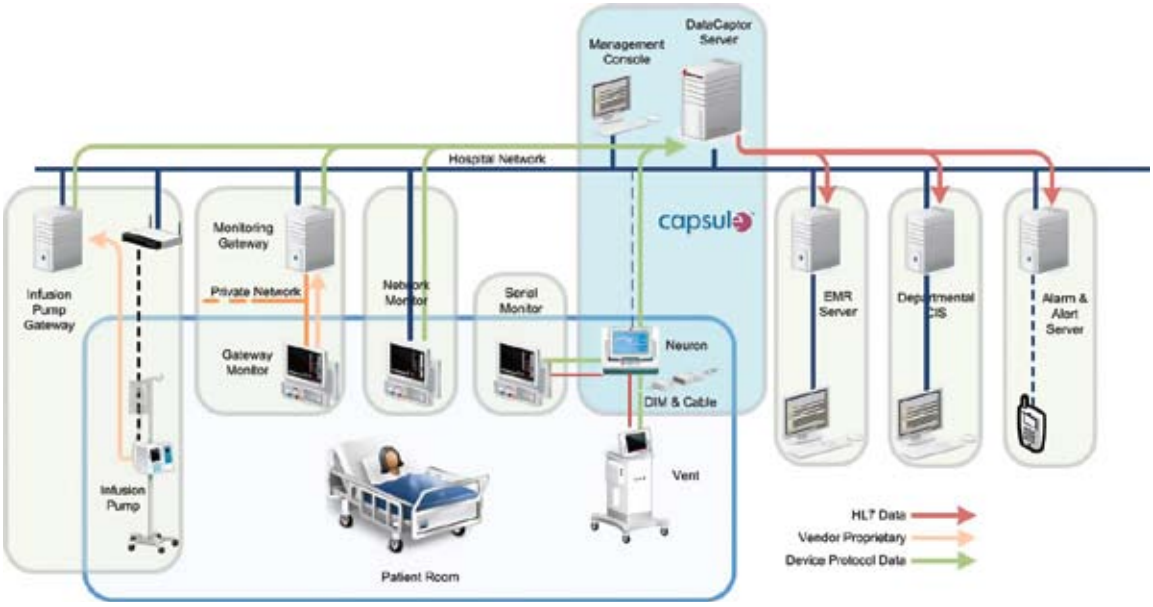
The use of Capsule as an MDDS integration vendor solves all of these problems. It enables the hospital to choose any monitoring, ventilator or other technology vendor without regard to information integration issues. That means that smaller companies like Nihon Kohden, which offers a 5-year warranty and more aggressive pricing, can be just as easily selected and integrated as larger, more expensive ones. This makes sense because the savings obtained by choosing less expensive monitoring providers will more then offset the investment required in the Capsule integration solution, providing a rapid return-on-investment (ROI). This can be critical during economic times like these when hospitals are limiting their purchases to critical technologies and comparing alternatives based on the total cost of the investment and not just the initial purchase cost.

Optimizing Data Integration The idea in optimizing information is to get all the data FROM every device to one location (in Capsule's case, the DataCaptor Server), and then to sort through it and deliver that data TO all the clients who are looking for it – in many cases multiple clients.

The Capsule DataCaptor allows all infusion pump vendors to send their data to any/all EMR or CIS/EHR vendors, and in those cases where the monitoring vendor uses Capsule interfaces, can send it to a bedside monitor, as well as from the DataCaptor. In fact, interfaces from similar devices can be consolidated to different gateways (as shown on facing page - top). Capsule offers bidirectional HL7 interfaces to Epic, Eclipsys, Meditech, McKesson, Cerner, GE's Centricity systems and other EMR vendors. Capsule provides a pathway into the EMR and HIS (Hospital Information System).

Because Emergin is a system that the DataCaptor Server is interfaced to, the Capsule/Emergin approach provides a method of wirelessly forwarding messages to the patient's mobile caregiver, completing the missing link from the monitoring system to the mobile caregiver. This enables caregivers to carry ONE device, usually an in-hospital, graphically-enabled VOIP (voice-over-Internet protocol) telephone. Data or an alert from any device feeding DataCaptor is then forwarded through Emergin to reach the caregiver for that patient, as a secondary alarm notification. The audit trail is maintained (by Emergin) of the receipt and the delivery of the message, and the acknowledgement of the delivery, or notification of whoever else it was forwarded/escalated to – if the primary caregiver did not acknowledge it.

Patient Safety Improved by FDA-Scrutiny The handling of data and messaging alerts/alarms has patient safety implications. If an interface to a device providing data is written incorrectly, it



can potentially have an adverse affect on the device to which it is interfaced. These interfaces have to be updated and validated (a time consuming and expensive affair) whenever a manufacturer introduces a new device. Once that update to Capsule is made, the data will flow into all of the other systems the DataCaptor directs it to.

In performing a risk assessment for a Medical Device Data System (MDDS) in this environment, it is possible that an MDDS could initiate a command to a medical device that results in an unintended operation of the device. If that device happens to be a Class III, life support device, the consequences could be significant. For example, it has been shown through actual testing that some infusion pumps can be put into unsafe modes or even crashed entirely from signals they receive from devices attached to their serial ports, which are supposed to be only data-out (one-way) ports.

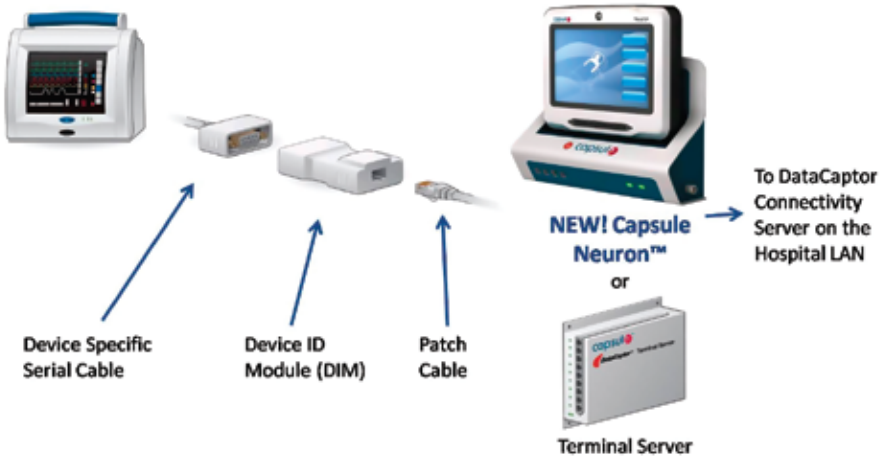
The normal operation of any MDDS typically involves sending commands to medical devices to "poll" a device to initiate a data transfer. This communication can be handled in a number of ways, including direct cabled connections, or over computer networks using both wired and/or wireless networks.

The components used in the Capsule system have been FDA cleared. Capsule is the only neutral MDDS that has FDA 510(k) clearance of any kind. And Capsule has gone one step further by filing for an FDA 510(k) Class II clearance, which is the same level of classification as a patient monitor device. Capsule has been providing interfaces for over ten years by extracting data from a wide range or medical devices.

The Capsule Neuron™ – As Safe As It Gets To further Capsule's enterprise-wide integration strategy they are launching a new bedside platform for managing device connectivity, the Capsule Neuron. The Capsule Neuron not only brings device connectivity status to the point of care, it is also the platform of the future designed to enable an expanding set of solutions to meet hospitals' evolving device, data and patient-device association needs.

This safe and reliable Capsule data interfacing and integration technology provides a single point of consolidation to any secondary alert/alarm messaging technology that hospitals are also using to provide an integrated, standardized, vendor-neutral approach to delivery of clinical information (and alerts) to caregivers. Moreover, it works well as a component of an enterprise-wide integration strategy.

Hardware Components for Serial Connectivity at the Bedside

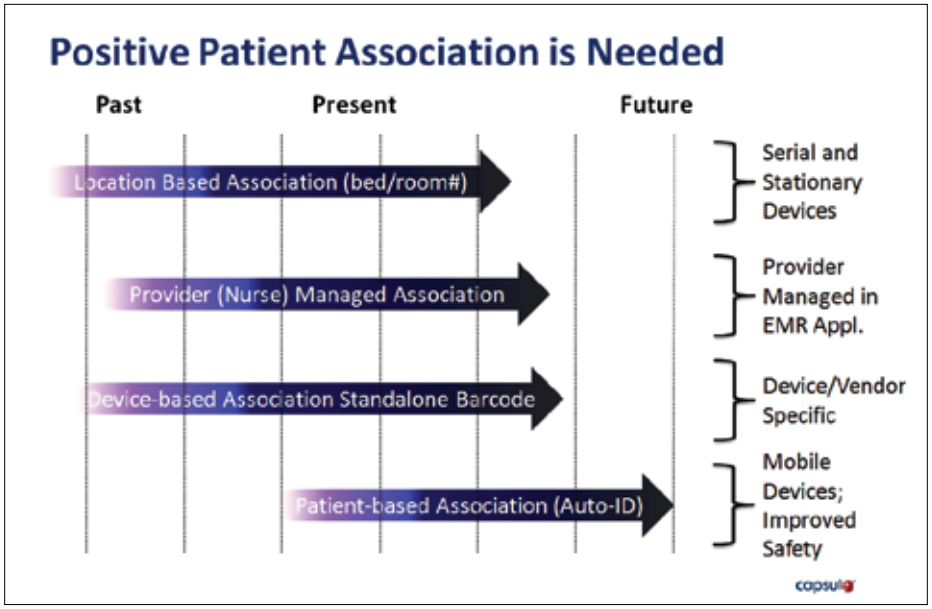


For example, we have written about the Emergin (now Philips) Integration Framework in Industry Alert previously. Capsule is an ideal "front-end" to that technology since it does interface to infusion pumps and ventilators and other devices that Emergin does not. It also provides an FDA-cleared integration, something that Emergin also does not provide (at this writing).

Patient Identity (Positive Patient Association) Issues The healthcare environment is becoming ever more mobile and wireless. In general wards, patients are often well enough to ambulate, taking (pushing) their monitoring devices and IV-mounted infusion pumps with them. Increasingly such devices are equipped with wireless LAN so that they can potentially leverage the 802.11b/g/a or "WiFi" (802.11b) networks that hospitals are deploying. The challenge is to make certain that all data is identified with the correct patient.

Over the Horizon-Automated Patient ID For a long time hospitals have sought a way to reduce cabling complexity in crowded patient rooms, especially around ICU patients. This can be done by using wireless cable eliminators. Indeed, GMP Companies (Ft. Lauderdale, FL) has done this already with patient ECG cables, but again partial solutions aren't scalable. This also needs to be done for ventilators, infusion pumps and all bedside devices, not using a parameter-at-a-time approach.

Great Potential For Confusion Most IV pumps and other transportable devices have no notion of "patient identity", they just "infuse". When these pumps report data or alarms there has to be some way of associating that data with the appropriate patient. When a device is moved from bed-to-bed (patient-to-patient), that association has to be changed to link the new patient ID to the device and then data and alarms can safely be integrated with EMRs, CISs and patient caregivers. These systems have to know that the IV pump was removed from Tom Jones in bed 4B at 3:30 PM to across the room to Fred Smith in 4A, whose infusion data it is now sending. How do "downstream systems" know about that transfer and log data to the correct patient's chart? Depending upon a caregiver to remember to inform the system can lead to mistakes.



It's critical to positively associate a patient with every device attached to them, physically or wirelessly, because creating an optimal clinical workflow should be a key consideration, ideally by some proximity-sensing, auto-ID technologies, such as passive RFID.

RS-232 Non-Conformity All RS-232 data from the serial ports must be converted into positively-identified data and made available to downstream devices and caregivers. But there are some challenges to overcome.

One is lack of conformity. Based on Capsule's extensive experience, many devices simply don't conform to any serial data standard, despite being labeled RS-232. Some provide no power through the serial port that could be used to power a wireless ID adapter. Putting a battery in such an adapter that has to be frequently replaced or recharged creates its own problems.

A Look Ahead That is what Capsule's Neuron product will eventually enable. Capsule's goal is to provide the platform that will ensure that only properly identified data and alarm messages are transmitted and entered into a patient's record. Capsule's Neuron, and future companion products, will overcome the problem of transmission of misidentified information.

In addition, Capsule's Neuron will assist in overall patient care. For example, if an EMR has a "do not resuscitate" order in place on a patient, the Neuron bedside foundation will be able to sense a defibrillator in the patient's room and generate an advisory questioning the reason for the defibrillator. This provides information that enhances safety and tracks potential inappropriate therapeutic interventions – something that cannot be achieved if the hospital has aligned its messaging and data integration strategy with a specific medical device vendors.

When completed, the Capsule solution will provide a vendor-neutral, enterprise-wide front-end ID needed for positively-identified, information flows. Once device, clinical data and clinical orders are positively identified, mistakes are less likely. This will have important benefits for the future of healthcare delivery. The Capsule Neuron technology foundation is an advance whose time has come. Δ