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DEFINITIVE DIRECTION FOR EMERGING MEDICAL MARKET INTELLIGENCE™

SPYWARE



Advanced Monitoring Strategies for the Ambulatory Patient

New, Scalable Solutions Needed to Handle Higher-Acuity Patients in SDUs and on General Wards March 4, 1998, the following caption appeared on the front page of the Wall Street Journal: For Texas Station, HDTV Means Hospital-Disturbing Television.

Here's why the story made headlines in the mainstream media; it made the nation aware of potential interference issues for medical telemetry systems. In June 2000, the FCC ushered in the era of Wireless Medical Telemetry Service (WMTS). The FCC initially gave hospitals three years to migrate to the new frequencies allocated exclusively for WMTS. In September 2003, the American Hospital Association (AHA) reported that, based on its informal polling of hospitals, there had been virtually no migration of medical telemetry systems to the new WMTS frequencies. Our Reality Survey of over 3,000 U.S. hospitals shows that most hospitals have now changed into the new WMTS band. The early migration was out of the lower part (450-460 MHz.) of the UHF band. In the last 2 years, additional migration has been out of the upper part (460-470 MHz.) of the UHF band.

On October 15, 2003, the FCC extended the freeze for an additional 180 days and then once more through December 31, 2005. While many hospitals have migrated, a few are still in the process. Today, only about 10% of hospitals remain in the UHF band, at considerable risk to themselves and their patients. For many, the issue is one of risk management – staying with current systems to avoid the financial impact of migration while hoping new sources of interference do not impact their operations – which borders on “magic thinking”.

As a result of the extensive migration from older UHF bands into the new WMTS, there will be slow growth for traditional U.S. hospital ambulatory step-down telemetry units over the next few years; however, there is a new

market that is expanding – monitoring patients in hospital general wards (many of which are increasingly being equipped with bedside monitors).

Monitoring Beyond Traditional Telemetry Boundaries As U.S. hospitals ramp up to accommodate the healthcare needs of the rapidly aging Baby-Boomer generation, telemetry monitoring will be increasingly called upon to monitor these higher-acuity patients. Today, most hospital monitoring is located in traditional ICUs or telemetry step-down units that are already filled to capacity with critically ill patients. As a result, patients are increasingly being admitted to the general medical/surgical floors when they require monitoring.

Preparing to care for aging Baby-Boomers and 46 million currently uninsured patients who will at some point come under a national healthcare program, will require hospitals to re-think the design of their facilities, particularly their “general wards”. Many believe that as more acute and aging patients require precautionary or continuous monitoring, there will be monitoring on all general medical-surgical units. In the future, ICUs and traditional telemetry step-down units will still be needed to monitor higher acuity patients that require more nursing care and a higher nurse-to-patient ratio. General care areas will become tomorrow's new progressive care units.

Centralized Monitoring - Hospital Wide Some trend-setting hospitals have already implemented a wireless infrastructure to provide for centralized monitoring of patients in many nursing care units. Some of these facilities have designed central surveillance units to monitor large numbers of patients from one location, citing both improved quality of patient care and patient flow efficiencies. This allows a patient to be admitted to any nursing care unit, but still be monitored for cardiac, respiratory or other problems. It is useful

when a patient presents with more than one problem, such as a patient who has a diabetic or cardiac co-morbidity. With telemetry, any bed can become a monitored bed, making it easier to admit patients to any (appropriate) available bed. This strategy provides for the best nursing care for the primary diagnosis but with supplemental surveillance of continuous monitoring.

An approach like this can help a hospital that has a crowded emergency operation improve patient admissions. When monitored beds exist in multiple care areas, the numbers of patients that are held in the ED are minimized. We previously documented this scenario at Holy Name Hospital in Teaneck, New Jersey (see Holy Name Hospital Renovates Incorporating Nihon Kohden & Other Advanced Technologies, Industry Alert Vol. 6 No. 4).

What Parameters to Monitor? Many patients today present with respiratory or other conditions for which NiBP and SpO₂ are more sensitive parameters to monitor than just ECG (which may show changes too late to be useful). Post-surgical patients are a good example, as a possible complication can be pulmonary embolism. Currently most of these patients are not monitored post-operatively and have written orders for vital-sign assessments every four hours.

An early sign of pulmonary embolism is a subtle decrease in the pulse oximetry value – but if it is not monitored, it may be 4 hours before it is detected by manual spot check vital signs monitoring. Spot checks of this parameter are a risky approach to early detection of this important complication, whereas continuous surveillance of respiration rate, SpO₂, NiBP and ECG together would detect it almost immediately. The problem is, most conventional, patient-worn telemetry systems do not offer respiratory rate, SpO₂ and NiBP. There are many other scenarios where continuous monitoring of patients outside of the traditional monitoring

environment is beneficial, but often the decision to monitor patients in these settings is offset by technology limitations or staffing requirements.

On many general medical surgical units there are elderly patients whose clinical conditions require them to ambulate during their hospitalization. As a method of assessing their tolerance of this activity, the nursing staff can conduct basic, non-invasive monitoring of ECG, NiBP, SpO2 and respiration. This assures that they have the cardiac and respiratory reserves required for such ambulation. The respiratory monitoring is particularly important for patients who have been smokers, have asthma, emphysema or COPD conditions.

Selecting the Right Device for the Patient's Monitoring Needs To accomplish this type of monitoring, a monitoring manufacturer needs to provide patient-worn devices employing a wireless infrastructure that transmits the patient's signal to a central surveillance site or traditional central station.

An obvious disadvantage of some systems is that some key parameters are not incorporated into the patient-worn device, but rather are incorporated into a separate patient monitor that is mounted on a roll around stand that the patient becomes tethered to and must push (or carry in their hand) as they ambulate. Even if the monitor is light weight, it still consumes one of the patient's hands, which for elderly patients who have balance problems, may limit their ability to get in and out of wheelchairs or to steady themselves when they are losing their balance. Indeed, even a monitor as light as 2 pounds can become a burden to a 90 pound, elderly female with advanced COPD. When the parameters needed are in a separate device on a roll around stand, ambulation may require nursing assistance. In this era when hospitals are faced with a growing nursing shortage, such an approach is an inefficient use of a very limited resource – nursing staff.

Battery Life Considerations Battery life of ambulatory telemetry is always a consideration. Many of the older generation telemetry systems had very limited battery life, in some cases less than two days. Battery life of portable monitors were even more limited, often ranging from only 2 to 6 hours.

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This presents a problem when a patient is sent off a nursing unit for a test that may take more than 2 hours, particularly if a record of the patient's vital signs is required during this stressful situation. Approaches that use monitors on IV poles need to be plugged in to recharge as soon as the patient returns to the room, or if the battery runs low during the test, will require the patient to be seated near an electrical outlet, which is not always conveniently available in many existing hospital diagnostic areas. Such limitations affect the patient's ability to toilet themselves and may contribute to the impression of poor care by the patient. Fortunately, some monitoring companies are finding ways to offer next-generation, patient-worn telemetry systems that allow ambulation and provide adequate battery life to overcome these problems. Below we have listed some of the characteristics of systems that enable telemetry surveillance of patients located in any ambulatory environment.

1. Patient-worn devices should be very lightweight and truly portable – the patient should be provided with total freedom of ambulation, the monitor should be battery-operated and patient-wearable.

2. Energy efficient – The monitor should operate on battery power for at least 24 hours for all parameters and longer when NiBP is not monitored.
3. The patient-worn unit should be flexible enough to monitor any combination of multi-vector ECG, NiBP, SpO2 and respiration.
4. The telemetry system should minimize nursing interventions or equipment care; nurses on general wards have many patients to care for.
5. The telemetry system should monitor and transmit all alarms – including arrhythmia notification – to a central station (or remote surveillance site).
6. The monitor should be capable of transparent and automatic transfer of all collected patient vital signs data to other clinical areas or the hospital's information system repository.



Nihon Kohden Emerges by Introducing Technologically-Innovative Solutions Over the last several years, MSP has watched as Nihon Kohden has become one of the fastest-growing monitoring companies in the U.S. marketplace. Year upon year Nihon Kohden's unit sales and market share have grown very significantly, a pattern we expect to see continue into 2006. NK has done this by displacing both smaller



specialty monitoring companies and larger, facility-wide suppliers – a rather remarkable feat for an emerging monitoring company. Why have they been so successful?

Nihon Kohden's ability to offer an array of innovative monitoring products useful across a variety of departments – both wired and wireless – and their ability to connect information on a highly robust network has contributed to their success. The remarkable value of their systems (which are typically 20-30% less than larger competitors) and their 5-year warranty have become a compelling combination to many hospitals seeking value but unwilling to compromise state-of-the-art design. Service quality has also made a significant contribution to their success.

MSP Identifies NK for Outstanding Service in 2004 and 2005 Each year MSP conducts an annual survey of all U.S. hospitals, of which about 65-70% respond. This survey measures a variety of parameters related to the quality of vendor service – such things as: the knowledge of the vendor's service desk personal, the time to arrive on site, the ability to fix a problem on the first visit, the cost of the service, the reliability of the equipment and others. This data is measured from the input of over 2,700

U.S. hospitals, making the results far more accurate than any other survey. In both our 2004 and 2005 Vendor Service Quality Reports (available at www.medsp.com), Nihon Kohden was noted both years, along with Philips, as the two best monitoring companies for overall service quality. Nihon Kohden also was tops in service value as their unprecedented five-year parts and labor warranty for all bedside monitors, transmitters, receivers and anesthetic agent analyzers makes after sale support virtually free.

The value of Nihon-Kohden products has been enhanced again by the introduction of the first transmitter designed to monitor ECG, NiBP, SpO2 and respiration in the WMTS band – the new NTX, patient-worn transmitter (shown above). This new transmitter allows Nihon Kohden to continue to expand its role as an enterprise-wide monitoring supplier by offering a product for surveillance in both traditional telemetry step-down units, but also for the emerging general ward telemetry surveillance market – the only component of the telemetry market that is poised for rapid growth over the next 4 years.

The NTX enables hospital staff to monitor higher acuity patients admitted

to lower cost clinical settings. The NTX is unique among other transmitters not only in the number of parameters, but in its design. The NTX allows patients to ambulate with a single ergonomically designed, patient-wearable, wireless monitor without the restrictions found in traditional telemetry or bedside monitors. The design of the NTX allows it to be worn either in the cuff or around the waist, similar to a Holter-style recorder.

Extremely comfortable to wear in either location, the NTX is lightweight and can operate for a minimum of 24 hours on three AA batteries while processing up to eight vectors of ECG, respiration, continuous SpO2 and NIBP with automatic inflations set at one-hour intervals. This frees the patient to ambulate without dragging along an IV roller pole and monitor and contributes to a better (and safer) in-hospital patient experience.

The NTX utilizes Nihon Kohden's unique miniaturization technology that provides more telemetry capabilities and value. One of Nihon Kohden's first technological advances was their unique "Smart Modular Cables", achieved by miniaturizing the circuitry found in traditional bedside modules and embedding it directly into the patient cables. The result was a truly functional, modular bedside monitor offering



a full spectrum of parameters and arrhythmia monitoring priced almost 20-30% lower than traditional modular monitors, a value that has been noticed by a growing number of hospitals. The same miniaturization technology was applied to capONE mainstream CO₂ technology specifically designed for non-intubated patients. Now that technological prowess is again manifested in the NTX, a breakthrough in multi-parameter, patient-worn ambulatory monitoring.

One strength of the NTX is that it connects to the Nihon Kohden monitoring network – making it ideal for “mission control” type, central surveillance configurations (where trained monitoring technicians can oversee the activities of many patients and report back to the caregivers any adverse changes or negative trends occurring with patients’ vital signs or ECG rhythms).

In anticipation of the NTX product release, Nihon Kohden made two significant changes to their central station software to further enhance the clinical utilization of the NTX. The first

change is that the user can turn ECG monitoring on and off from the central station, so the NTX can be converted instantaneously from a simple vital signs monitor (NiBP, SpO₂ and pulse rate) to a telemetry transmitter that can support a high variance in patient acuity.

NK has succeeded by displacing both smaller specialty suppliers, and larger, facility-wide suppliers – a rather remarkable feat for an emerging monitoring company.

Second, a new feature called Device Transfer was added, which makes Nihon Kohden’s central networking system one of the few patient-centric systems in the industry. With Device Transfer, all patient information, including waveforms, vital signs and full disclosure data, can be acquired and transferred seamlessly from one clinical unit to another, regardless of the device that is being used to acquire that data. Being patient-centric empowers

hospitals by giving them the ability to maintain a seamless patient record across the patient’s entire admission.

These two features were added to the Nihon Kohden monitoring network that already featured a very robust yet inexpensive HL7 gateway server that allowed industry-standard transmission of all patients’ vital signs data to the hospital’s record-keeping system or other HL7-compliant systems or repositories. That makes Nihon Kohden a good partner for enterprise-wide data integration – an increasingly important issue today.

While many monitoring vendors have products optimized for the traditional, ECG or ECG/SpO₂ telemetry step-down markets (which will have very low volume over the next 4 years), Nihon Kohden has cleverly positioned itself to participate or lead the conversion of the general ward from manual, spot-checked patient surveillance to continuous, networked surveillance using their innovative, patient-worn telemetry systems. Δ

