compliance

Labeling solutions for medical applications

Peak-Ryzex offers labeling, track-and-trace products for Zebra Technologies' healthcare solutions, increasing reliability and patient safety.

BY ARIELLE CAMPANALIE

Improper labeling of healthcare products is an easily avoidable mistake that can cause lethal outcomes.

Peak-Ryex and Zebra Technologies have partnered to offer barcode labeling systems in the healthcare industry for patient identification, mobile specimen collection, patient information tracking, unit-of-use packaging, and to improve inventory controls with smart labels.

Today's Medical Developments spoke with Tom Heitman, manager of solutions consulting at Peak-Ryzex about the system.

TMD: **Can you explain the history the of Peak-Ryzex and Zebra Technologies partnership?**
Heitman: Peak-Ryzex has been a premier partner with Zebra for many years. We continue to provide labeling and track-and-trace solutions to our customers across many vertical markets, including healthcare. These solutions are sometimes as small as printing solutions with break-and-fix services and other times as large as complete end-to-end printing, tracking, and integration solutions.

TMD: **How are labels manufactured?**
Heitman: Peak-Ryzex sources its labels from manufacturing sources such as Zebra Technologies that meet or exceed requirements for compliance, durability, and adhesion based upon the specific parameters around our customers' needs and items to be labeled.

TMD: **What are some examples of Peak-Ryzex's labeling system?**
Heitman: Any tangible item (product, assembly, asset, storage location, medical device, etc.) may have a label designed and printed on-demand containing barcoded unique identifiers as dictated by both internal company and external compliance requirements.

Printing on-demand provides our customers the ability to dramatically reduce costs and effort associated with purchasing and maintaining inventory on pre-printed labels for all devices or products. It also provides opportunities to generate labels for purposes other than compliance.

Unique barcoded identifiers enable our customers to use these labels for both internal tracking purposes and customer or governmental compliance.

TMD: **How were labels designed?**

Heitman: Since our solutions are geared heavily toward printing on-demand, the label format designs are created using what you see is what you get (WYSIWYG) label-design software through collaboration between the customer and Peak-Ryzex resources.

The attributes of the physical media are derived using our wealth of experience in the industry and input from the customer on environmental and target item attributes.

In some instances, the use of pre- printed labels works best to meet requirements. Peak-Ryzex also offers custom, pre-printed labeling solutions to fit these situations. Based on the attributes of the item/device being labeled, the size and layout of the label will deviate, while the content for specific types of labels (e.g., UDI-compliant) will remain constant.

TMD: **What are the benefits of using Peak-Ryzex's medical labeling products?**

Heitman: Labels produced – especially for unique device identification (UDI) compliance – contain barcodes. These labels not only meet UDI requirements, but also contain barcoded data attributes, such as serial numbers and lot numbers. Customers that leverage these barcodes to track inventory receiving, movement, and storage in their organizations benefit greatly by increasing traceability.

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TMD: **Why are Peak-Ryzex's medical solutions critical to healthcare applications?**
Heitman: Our solutions can help our customers achieve compliance with specific industry mandates, improve internal tracking of inventory/manufacturing, and reduce costs/effort of maintaining an inventory of pre-printed labels.

TMD: **Where else are Peak-Ryzex's solutions implemented?**
Heitman: Our labeling and tracking solutions are implemented across many vertical markets. Our solutions have been implemented in compliance, inventory asset tracking, and transportation.

Peak-Ryzex Inc.

www.peak-ryzex.com (http://www.peak-ryzex.com)

Zebra Technologies Corp.

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HEARTLANDS HOSPITAL CASE STUDY

In 2004, the United Kingdom's (U.K.) National Health Service (NHS) faced more than $6 million worth of clinical negligence claims. One key cause was patient misidentification, which the National Patient Safety Agency states causes 19% of all hospital errors.

The U.K. government estimates that errors associated with mistaken identity costs the NHS approximately $3 billion annually in extra bed days. Similarly, the NHS continues to come under attack for inefficiency. Despite this, many hospitals have been unable to significantly improve accountability. Operation delays are one of patients' top complaints.

Currently an estimated 80 minutes per day is wasted due to slowness in getting patients to the operating theater on time.

The Birmingham Heartlands Hospital is part of The Heart of England NHS Foundation Trust. It is one of the largest in England serving half a million people and caring for 574,000 patients a year. Information accuracy is essential for providing the best possible patient care, so the Birmingham Heartlands Hospital needed to develop a system for managing patient identification throughout the operation process.

Radio tagging to avoid misidentification

"We wanted to take advantage of the latest technology to implement new patient safety standards and improve the efficiency of our operating theaters," says consultant surgeon David Morgan. "We rely on patients' wristbands to give us the right information to provide every aspect of their treatment from administering medication, to transfusing blood, to carrying out surgical procedures. Given its critical role in patient care, any system we developed had to based around the radio-frequency identification (RFID) wristband."

Heartlands Hospital worked with a specialist healthcare technology provider to develop a process that used technology to drive patient safety and efficiency. The resulting solution combines RFID tagging with real-time process software using personal digital assistants (PDAs) and Zebra printers and wristbands. When admitted, the patient is photographed and given a printed wristband with an embedded RFID tag. The patient's digital image is part of the patient record identification through the operation process. All clinicians involved in the operation have wireless PDAs for viewing operating lists and patient records. On approaching the patient, clinicians use their PDAs to identify the patient or scan the patient's RFID tag. All pre-operative checks are then recorded on the PDA which immediately updates the operating list.

A traffic-light warning system, which changes from red to green in the patient record, is used to ensure all the pre-surgery required checks have been performed. When patients are sent to theater, the reader identifies them from the RFID tag and retrieves the appropriate record on the screen, ensuring there is no opportunity for misidentification.

Theater efficiency is automatically measured as each step in the process is recorded with a time and date stamp – the procedure is coded by the operating surgeon to improve efficiency and further reduce administrative time.

Reducing operation waiting times

The initial pilot in the ear, nose, and throat (ENT) day surgery unit enabled the hospital to complete one extra operation per day, equivalent of an additional 672 simple or intermediate procedures per year. This generates an additional unplanned income of between about $100,000 and $400,000 per year (depending on the type of procedure). In addition to ensuring the safety and efficiency of the operation process, the system can support other processes such as deep vein thrombosis (DVT) risk assessment, admission, discharge & transfer (ADT), and any other procedures that require identification verification. Similarly, it can be used to help monitor infection linked to patients, beds, and staff. Also, if a biopsy or test is undertaken in theater, the correct patient label can be printed immediately to avoid mislabelling.

"We have not had a single mistake while using the system. Patients feel more confident as we're taking safety to a higher level," Morgan continues. "The theaters run more efficiently because there is less waiting time for patients. The accuracy of coding has now increased to almost 100% as the coding is done by the operating surgeon on a PDA at the time of surgery. What's more, staff are able to spend more time with their patients as a result of less paperwork – further helping to improve patient satisfaction."

Today the system is used in four wards and four operating theaters, with plans to extend the roll-out within the next 12 months. www.zebra.com (http://www.zebra.com)

CONSIDERATIONS FOR THE LAB

Patient ID verification – Achieve compliance with the Joint Commission's National Patient Safety Goal (NPSG) to improve the accuracy of patient identification. Meeting the patient ID goal requires that medical staff use at least two patient identifiers whenever they collect lab samples and to label containers used for blood and other specimens.

Increasing information – A standardization of electronic healthcare records means the gathering, storing, and linking of more information throughout the patient care process. In addition, blood, tissue, and cellular therapy products must be compliant with the ISBT 128 identification standard of labeling – a process not attainable with manual labeling.

Patient privacy compliance – HIPAA mandates the use of technologies and processes to protect patient privacy. This requirement extends throughout the healthcare lifecycle, including electronic medical record (EMR), samples, medications, and independent laboratories.

Label sizing – A label provides the critical link between the physical specimen and the information in systems associated with it. Test tubes, blood bags, slides, and hermetically sealed containers all require specific label dimensions.

Cost-effective label creation means using versatile printing technology that produces a label in the exact size for the task.

Legibility – Medical centers have found that color-coded labels provide a visual indicator of tests the lab must perform, saving time. Because each sample and patient are unique, healthcare providers need a labeling solution that replaces preprinted labels with a system that creates labels on-demand, and that will not smudge when exposed to liquids.

Durability – Pathology labs often must store specimens for up to 20 years, which means labels must be durable enough to last and afford resistance to chemicals. In areas such as blood banking and cellular therapies, products undergo cryopreservation, and then are stored for an extended period before patient transplantation. www.zebra.com (http://www.zebra.com)

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