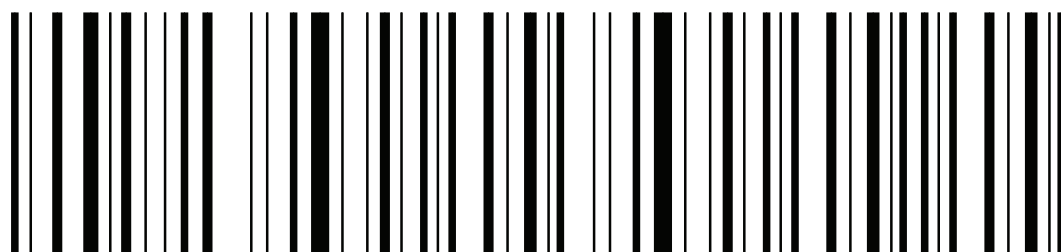


Adopting Bar Code Labeling in Hospital Pharmacies



A P P L I C A T I O N W H I T E P A P E R



Zebra Technologies

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Executive Summary

One of the most proven and effective methods to prevent medical errors is to use bar coding to identify medications at the unit-dose level for dispensing and administration. By taking action to ensure all medications used in the hospital include a bar code, pharmacists can set a strong foundation for patient safety initiatives and align their organization with patient safety goals established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Society of Health-System Pharmacists (ASHP).

This white paper will illustrate how bar code systems improve patient safety; summarize the ASHP, JCAHO, and FDA policies and recommendations that are driving the current surge in bar code-based patient safety programs; present bar code marking options for pharmacists; and provide guidance for developing a practical strategy for bar code-based patient safety programs.

Introduction

The FDA investigated bar code medication administration processes and concluded they would reduce medication errors by 50 percent if fully implemented. This study led the agency to require pharmaceutical manufacturers to apply bar codes at the unit-of-use packaging level by April 2006. The actual impact of managing medication administration with bar codes will likely be even higher; early adopters have reported error reductions in excess of 80 percent. Pharmacy bar code verification procedures can also prevent many dispensing errors, which are the root cause of about 20 percent of medication errors¹. Wesley Medical Center in Wichita, Kan., documented a 96 percent reduction in dispensing errors after implementing bar code procedures².

Recommendations by ASHP encourage hospitals to build on the foundation of bar coded medications advocated by the FDA. The ASHP Health-System Pharmacy 2015 Initiative calls for 75 percent of hospitals to use machine-readable coding to verify medications before dispensing. The initiative also sets a goal that 75 percent of medications be automatically recorded prior to administration. The ASHP issued separate policy statements calling for all medications to be marked with machine-readable codes, and for pharmacists to take leadership in patient-safety efforts. A new JCAHO National Patient Safety Goal for 2006 requires labeling for all medications and medication containers. While JCAHO does not specifically require bar coding, the technology is an outstanding option because of the proven accuracy and safety benefits it provides.

ASHP Policy Statement: Machine-Readable Coding and Related Technology (0308)

Source: Council on Administrative Affairs

To declare that the identity of all medications should be verifiable through machine-readable coding technology and to support the goal that all medications be electronically verified before they are administered to patients in health systems... To strongly encourage health systems to adopt machine-readable coding and point-of-care technology to (1) improve the accuracy of medication administration and documentation, (2) improve efficiencies within the medication use process, and (3) improve patient safety; these systems should be planned, implemented, and managed with pharmacist involvement and should be in all areas of the health system where drugs are used.

This policy supersedes ASHP policy 0204.

1. Hospitals and Health Networks, April 2004.

2. Robert Ragan, Jack Bond, Kelly Major, Tim Kingsford, Leslie Eidem and James C. Garrelts, "Improved control of medication use with an integrated bar-code-packaging and distribution system," American Journal of Health-System Pharmacy, Vol. 62 May 15, 2005.



Pharmacists can lead bar code-based patient safety initiatives by developing a comprehensive program that ensures all forms of medication are bar coded at the unit-dose level, implementing pharmacy labeling and scanning processes to prove the effectiveness of bar code control, and encouraging implementation of automated medication administration systems.

Fundamental to this strategy is understanding bar code marking needs and the limitations of the FDA requirement. The following sections explain how patient safety programs depend on bar codes and why hospital pharmacies should start planning bar code marking systems.

Understanding Marking Issues and Options

The FDA unit-of-use marking requirement for manufacturers is not sufficient to satisfy the information needs of most patient safety programs. The more medications that are marked with bar codes, the more effective the programs will be. Hospitals routinely repackage medications that come in unit-of-use packages into specific unit-doses, making manufacturer-applied bar codes at the former packaging level insufficient for the latter. Some are concerned that manufacturers will also eliminate unit-of-use packaging for some pharmaceuticals rather than code them. Furthermore, compounds are exempted from the rule. Because IV mixtures frequently contain patient-specific additives, the pharmacy should have an on-demand printing system capable of producing patient-specific bar codes. These examples show the limited reach of the FDA requirement and illustrate the demand for in-house bar code marking.

Hospitals have several options for overcoming the shortfalls of FDA-mandated supplier bar code marking, including both manual and automated repackaging, overwrapping, and other on-demand bar code printing. Many early adopters of bar coding use a combination of methods to meet all their needs, and other hospitals will likely follow suit. Regardless of the techniques used, hospital pharmacies should establish thermal printers as the foundation of their in-house bar code labeling program. Thermal bar code printers support all pharmaceutical bar code format and data options, and excel at producing high-quality symbols suitable for vials, syringes, ampuls, IV bags, tablets, and other medication forms. Thermal printers also provide strong total-cost-of-ownership (TCO) advantages compared to other marking methods. They can be easily integrated with legacy pharmacy information systems and will not need to be replaced as additional applications and systems are developed.

Many pharmaceutical packaging and marking systems already use integrated thermal printers to produce medication and bar code labels. Thermal printers can also be used to support equipment that doesn't offer bar coding capabilities. For example:

- **Repackaging** equipment is an efficient way to prepare unit-of-use packages from bulk liquids and oral solids. If the repackager does not include a bar code label printing capability, a separate printer can be used to create labels for manual application during the packaging process. This process adds some time to repackaging operations, but has been found to reduce overall labor costs because it facilitates efficiency gains in other processes³. The practice is extremely cost-effective when the patient safety and error prevention benefits are considered.

3. Mark Neuenschwander, Michael R. Cohen, Allen J. Vaida, Jeffrey A. Patchett, Jamie Kelly and Barbara Trohimovich "Practical guide to bar coding for patient medication safety," American Journal of Health-System Pharmacy, Vol. 60 p. 776, April 15, 2003.



- **Overwrapping** is very effective for labeling irregularly shaped objects such as syringes, vials, and ampuls, and for medications that are placed into bags. As with other forms of repackaging, hospitals may contract a supplier to provide overwrapping for select items. If in-house overwrapping is done, thermal bar code printers are an ideal complement to produce labels for the bag, which can be encoded with medication-specific or patient-specific information and printed on demand.
- **Automated dispensing** systems rely on bar coded medications and cassettes for their automatic medication selection and counting processes. Pharmacists can create cassette or individual medication labels so medications can be loaded into automated dispensing machines.

Bar code label printers are also an option for producing unit-dose labels for compounds, IVs, and other prepared medications. They can also be used to re-label items whose manufacturer-supplied bar codes do not meet the hospital's system needs. The following sections provide a brief overview of how bar codes on medications can be used to improve patient safety.

Dispensing Applications

Pharmacists most commonly take advantage of bar code processes to verify and record medication dispensing. Typically, the pharmacist scans the unit-of-use bar code on each dose dispensed to fill a prescription. The National Drug Control (NDC) number is encoded in the bar code and is automatically recorded when the symbol is scanned. The NDC is an FDA-standard 10-digit identification number that identifies the item by labeler (manufacturer, repackager, or distributor), product code (which defines the product by strength, dosage form, and formulation), and package type. The NDC number usually contains a leading zero to create an 11-digit number, since the 10-digit code can be in a 4-4-2, 5-4-1 or 5-3-2 format. The scanner is interfaced to a database or other software application that checks the NDC against the prescription order to validate that the correct medication and dosage were dispensed. An immediate alert is issued if there is a discrepancy. Lot codes and expiration dates are also commonly encoded on unit-of-use labels and can be used to trigger appropriate alerts. Most bar code systems also automatically record the date and time of all transactions to provide an audit trail.

The pharmacist may also print a unit-dose label with information included as human-readable text and in a bar code, and scan it to record the release of the prescription. The nurse or aide who receives the dose may also scan the bar code and their bar coded ID badge to record custody.

The same bar codes used for automated dispensing also drive bedside medication administration applications, which are at the heart of bar code patient safety programs. In automated medication administration, bar code scanning is used to drive a computerized Five Rights check. The process is similar to dispensing verification, but can prevent many more errors. Prior to dispensing medication, the nurse scans the bar codes on their own ID badge, the patient wristband, and the medication-specific unit-dose label. Application software on a handheld or cart-mounted computer quickly performs a database check to confirm the medication to be dispensed conforms to an order for the patient. The encoded NDC number provides the medication strength and other information the system needs, but does not reflect the prescribed dose. The software checks the NDC data against the prescription order, then issues an approval to dispense or an alert, and the transaction time is automatically recorded.

If dispensing verification or bedside medication administration systems are in place, the pharmacist will most likely need to create patient-specific bar code labels to support the application. Pharmacists should use



on-demand label printers to mark medications that are prepared specifically for a patient, such as compounds and IVs with patient-specific additives, partial doses, pediatric doses, etc. Tracking by NDC number is insufficient for patient-specific labeling because the NDC does not identify the final specific substance. The patient-specific bar code is usually a unique serial number that corresponds to a database record that contains the formulation and patient identification details. Thermal printers are an outstanding option to support this operation because they can quickly and easily produce variable-information bar code labels, accept media suitable for labeling curved or irregular surfaces such as IV bags or vials, and are available in compact sizes that save valuable counter space. Thermal printers also produce text and graphics, so they can be installed to support legacy pharmacy labeling processes, or to support the JCAHO medication labeling safety goal, until bar code systems are introduced.

Bar code administration and dispensing applications are proven to reduce errors and improve patient safety. They present hospitals with an excellent return on investment (ROI) opportunity because they can be implemented independently of much more expensive computerized physician order entry (CPOE) and electronic medical record (EMR) systems. Software providers offer automated dispensing applications that can be integrated with legacy pharmacy information systems, so there should be no need for a major IT upgrade. The following sections present tips for developing a strategy for developing bar code-based patient safety projects.

Hospitals can also use the information captured by bar code scanning for patient charging, material and inventory management, order generation, and even product authentication. Zebra's white papers "It's All in the Wrist: Improving Patient Safety with Bar Code Wristbands," and "Patient Safety Applications of Bar Code and RFID Technology" provide more information about these and other applications. Visit the Resource Library section of www.zebra.com to download these white papers and related case studies.

Developing a Bar Code Strategy

Decisions about which medications to bar code first, what information to include, and which symbology to use are fairly easy to navigate once the overriding project goals are established. The goals will determine the processes to be developed, and the processes will determine which pharmaceuticals need bar codes and the information to encode in the symbols, which in turn will guide symbology selection.

The incidence and severity of medication errors should be factored into project goals and prioritization of medications to be managed with bar coding. Dispensing errors clearly contribute directly to adverse drug events (ADEs). The FDA studied the incidence of ADEs and found they range from 2.4 percent to 6.5 percent per facility, with a mean rate of 4.3 percent. For its analysis, the FDA used an average cost per ADE of \$2,257, although many other estimates have been put forth, most of them higher. Therefore, hospitals spend an average of \$9,705 per 100 admissions in treating the effects of ADEs (4.3 ADEs per 100 patients x \$2,257 per incident). This equates to ADE-related costs of \$97 per admission.

JCAHO 2006 National Patient Safety Goal: Improve the Safety of Using Medications

New requirement: Label all medications, medication containers (e.g., syringes, medicine cups, basins), or other solutions on and off the sterile field in perioperative and other procedural settings. Applies to: AMB, CAH, Hosp, OBS.

Source: *Joint Commission on Accreditation of Healthcare Organizations.*



Medication errors are the cause for 5 percent of malpractice claims according to an analysis by Dr. Byron J. Bailey, FACS⁴. In 2000, the average jury award for medication error cases was \$636,844, according to Jury Verdict Research⁵. These figures help determine the value of using bar code procedures to prevent dispensing and administration errors, and for determining how comprehensive patient safety programs should be.

Once the priority drug list is established, the pharmacy should audit its inventory to determine which drugs are already sufficiently labeled. The bar code marking task may not be as large as it might seem—Beloit Medical Center found that more than 30 percent of the items in its formulary already carried a bar code, as did nearly 50 percent of the pharmaceuticals at Brigham and Women's Hospital.

The pharmacy or purchasing department should also contact suppliers to learn their unit-of-use bar code packaging plans, and then create a list of pharmaceuticals that should be self-labeled to satisfy program goals. The organization will then have a good idea of the amount and type of unit-dose labels it will probably need to produce as the program evolves. With program goals and expected printing volume established, you can begin planning printing operations to efficiently satisfy label size, data content, symbology, and volume requirements.

ASHP states that the ultimate goal should be to bar code every drug in the pharmacy. Hospital pharmacies can begin with a limited program, perhaps starting with the 500 most frequently used drugs or with specific types of pharmaceuticals (e.g., IV mixture, Class 1 narcotic). Then, they can gradually expand it into a comprehensive program. However, to reiterate, automated bedside medication administration, wherein the nurse or aid scans the bar codes on their badge, the patient's wristband, and the unit-dose, is the optimal approach for maximizing patient safety. This point-of-care solution requires that all medications be bar coded at the unit-dose level.

Symbology Selection

Determining the best symbology to use depends on the type and amount of data to be expressed in the bar code, and the space available for marking. The same symbology doesn't need to be used for all items, because bar code readers can recognize and decode multiple bar code formats (the capability is referred to as "autodiscrimination" in bar code technical literature). There are more than 200 bar code symbologies, but only a few are appropriate for unit-dose identification. The leading candidates are favored because of their proven performance, suitability for the task, and support by international and industry standards.

The three leading symbologies for unit-of-use labeling are Code 128, Code 39, and the Reduced Space Symbology (RSS) family. Each is allowable under the FDA rule. The FDA did not allow manufacturers to mark products with two-dimensional bar codes, which are capable of encoding much more information than linear symbols in the same or less space. The FDA was concerned that the added cost of 2-D bar code readers would inhibit hospitals from implementing bar code applications. However, several healthcare organizations have successfully implemented 2-D systems, and there are ample bar code readers and printers available to support the technology. Leading symbology options are profiled below.

4. Byron J. Bailey. "Medical Liability Issues: Where Malpractice Claims Come From and How to Survive Them," July 2002.

5. Jury Verdict Research. "2000 Current Award Trends in Personal Injury, " June 2001.



Code 128

Code 128 can encode the full 128-character ASCII character set. It is popular because it is one of the densest linear symbologies, meaning it can encode information in less space than symbologies with lower densities. Code 128 is a variable-length symbology, so symbols can be as long as necessary to encode required data. Code 128 replaced Codabar as the standard for identifying blood products.

Code 39

Code 39 (also called Code 3 of 9) is one of the oldest and most widely used symbologies in industry. It is a variable-length alphanumeric symbology for encoding 26 capital letters plus numerals and seven special characters. An extended version is available that supports all 128 ASCII characters. Code 39 is less dense than Code 128, thus requiring more room on the package.

RSS

The RSS family of symbologies was created specifically for use in applications where space is limited. RSS-14 is an all-numeric symbology that is the leading option for unit-of-use pharmaceutical marking, but can also be used on wristbands. RSS Stacked is an alphanumeric symbology that provides additional data capacity by stacking a series of RSS symbols. Other symbologies in the RSS family, including RSS Truncated and RSS Composite, provide options for additional space savings and data capacity.

Data Matrix

Data Matrix codes won't be applied by manufacturers because it is a 2-D symbology, but it has a legacy of use in medication administration and other healthcare applications. Brigham and Women's Hospital chose Data Matrix because it allows them to include the NDC, lot number, and expiration date on small items. Data Matrix can't be read with laser scanners, but is aptly supported by other types of bar code readers and label printers.

PDF417

PDF417 is a two-dimensional symbology that can resemble a series of small linear codes stacked upon each other. PDF417 offers high data capacity in a relatively small space. Up to approximately 2,000 alphanumeric characters can be encoded in a PDF417 symbol, although symbols printed for unit-dose sizes would hold considerably fewer. PDF417 is a popular option for wristbands when organizations want to include information beyond the patient name or ID number.

Aztec Code

Aztec Code is a 2-D matrix symbology capable of containing from 13 to 3,832 numeric characters or 12 to 3,067 alphabetic characters. Aztec Mesas are Aztec Code-based supplements that can be added to linear bar code symbols to encode additional information. The resulting symbol is a composite of linear and 2-D symbologies.





Selecting a Printing System

The desired symbology, label sizes, and printing volume drive the printer selection and the best types of label media to use with it. Before evaluating specific printers, organizations should make a fundamental decision whether to use laser or thermal print technology. Thermal printers are purpose-built specifically for bar coding, while lasers offer familiarity because they are used in many pharmacies and offices. There are many important differences in how each technology handles unit-dose labels that must be considered when planning the print system.

The following factors must be considered when evaluating different print technologies and specific equipment:

- **What effect does variable data have on performance?** If lot codes and expiration dates are to be included in the bar code symbol, the printer must be able to process variable data efficiently. Variable data output slows some printers considerably, while others process variable data at their top print speeds.
- **Does standard equipment produce enough resolution?** Readable bar codes require sharp, clear edges. Requirements become more exacting as symbols get smaller. Users must pay particular attention to edge definition, which refers to the clarity and contrast of the dark and light edges within the symbol. Thermal printers are known for producing outstanding edge definition and symbol quality.
- **Is the desired symbology supported?** Some print technologies can only output symbologies commonly used for retail packaging. RSS support can be especially hard to find. Another factor to consider is the effort required to modify existing equipment to support desired symbologies. Questions to consider include: Can symbols be downloaded from software? Is new firmware required? Can users install it themselves or is a service call needed? Will the new symbologies strain system memory and performance? Is new equipment required?
- **Can the printer use appropriate supplies?** Unit-dose labeling often means using multiple label sizes and materials formulated to withstand cold storage, moisture, curved objects, and other challenges. The printer therefore must be able to produce sharp bar codes on these materials—without wasting media, jamming, or hampering productivity by requiring frequent media changes or troubleshooting.

To understand and appreciate the benefits that thermal technology has over laser for bar code label production you need a basic understanding of bar code symbols and how each print technology produces them. Scanners decode the information from bar codes by measuring the differences between narrow and wide elements, and the contrast between dark bars and light spaces. If the ratios or contrast are slightly off, the bar code may be difficult or impossible to read. The potential consequences of errors or incomplete information for medication administration and dispensing operations are simply too dangerous to risk insufficient symbol quality.

Laser

Laser printers work much like photocopiers; they project controlled streams of ions onto the surface of a print drum, resulting in a charged image. The charged image then selectively attracts toner particles, transferring the image onto the paper substrate by means of pressure. The pressure from the printhead and drum then fuse the image to the paper, creating the image.



Advantages

- Laser printers are good at producing bar codes on plain-paper documents.
- They can print high-quality text and graphics on paper documents and can double as a document printer when not being used to print bar codes.
- Bar code density and resolution are also quite high on laser printers, resulting in high-quality symbols.

Limitations

- Laser printers can be wasteful because they cannot produce single or small labels. A minimum of half a page of media is typically required for the printer to maintain control of the sheet. Unless the label is at least that size or multiple labels are needed at once, the remainder is wasted.
- Laser printer label adhesives must be carefully selected to ensure stability under the heat and pressure of the fuser. Otherwise, the adhesive may seep onto the printer mechanism, where it will capture stray toner, or may cause the labels to curl at the edges.
- Because of the pressures used in the image transfer process, many laminated label materials are not compatible with laser printing. Those materials that are compatible may not always be available in the sheet form necessary for laser printing.
- A laser-printed paper label has limited durability. Laser printers cannot produce chemical- or water-resistant labels and images.
- With laser printers, toner, drum, and supply costs can skyrocket when printing bar codes instead of typical text. While text printing requires only about 5 percent black toner, bar code needs can exceed 30 percent to ensure proper contrast between dark and light elements. Toner costs alone could be six times higher when printing bar codes rather than text.

Thermal

Thermal printing is classified as either direct thermal or thermal transfer. The two technologies are suited to different applications. Direct-thermal printers create images by using a printhead to apply heat to selected areas directly to the chemically treated label material. There is no ribbon or ink required. In thermal-transfer printing, the printhead heats a ribbon, which melts the image to the material. Thermal transfer is used for high-durability, long-lasting labeling applications. Direct-thermal printing is the technology of choice for most unit-dose labeling applications. It has many advantages and a few limitations.

Advantages

- Direct-thermal printing produces sharp print quality with good readability.
- Direct-thermal printers are simple to operate compared to most other print technologies, with no ink, toner, or ribbon to monitor and replenish.
- Because direct-thermal printers don't use ribbons, they protect patient privacy, which helps comply with HIPAA.
- With no supplies to replace other than the material to be printed, long-term maintenance costs and total cost of ownership remain low.



- Direct-thermal technology enables batch or single label printing with virtually no waste.
- With recyclable materials available, direct-thermal printers offer environmental economy.
- Direct-thermal printers, like thermal-transfer, are typically built more durably than dot matrix or laser printers, allowing reliable operation in industrial as well as office applications.

Limitations

- Direct-thermal printing is sensitive to environmental conditions such as heat and light. Long-term exposure to fluorescent light can reduce bar code quality. However, top-coated media is available to mitigate these effects, and direct-thermal labels are usually fully capable of meeting medication marking needs.
- Thermal printers accept roll media and cannot print 8 1/2- by 11-inch documents.

Zebra Pharmacy Labeling Solutions

Thermal printers from Zebra Technologies have been used to create millions of bar code unit-dose, prescription, and sample tracking labels in a variety of clinical settings. Zebra has worked with many leaders in bar code patient safety initiatives to develop printers and label supplies that meet healthcare providers' needs for reliability, performance, ease of use, and connectivity to information systems. Zebra® printers have many features and options that are highly advantageous for pharmacy labeling programs, including:

- **Outstanding print quality**—Thermal is the dominant technology used for on-demand bar code printing across industries. Zebra is a leader in the field, with more than 4 million printers sold. Zebra printers are engineered specifically to provide outstanding bar code print quality and to support the adhesive media used for unit-dose and other pharmacy labeling applications.
- **Symbology support**—All common bar code symbologies used for unit-dose labeling are supported, including 2-D symbologies. Zebra printers can produce multiple symbologies and graphics straight out of the box, with no upgrades or modifications required.
- **Label size and volume flexibility**—Zebra has models to meet all label size and printing volume requirements, including many printers that excel at producing high-quality small symbols for unit-dose labeling. Zebra also has a comprehensive range of label material so media can be matched precisely to usage conditions to ensure high performance and minimize waste.

Printers themselves are available in many sizes, ranging from extremely compact desktop models that fit easily into crowded pharmacy counters, to larger industrial units suitable for repackaging and other high-volume applications.

- **Media options**—Zebra offers label sizes and materials optimized for use with our printers that provide resistance to scratches, moisture, alcohol, and other exposures to provide reliable performance in pharmacy and patient care settings. Matching media to the specific printer model eliminates waste, optimizes bar code readability, and extends the life of the printhead.



- **Computer system compatibility**—To integrate with PCs, networks, pharmacy information systems, and other legacy IT systems, Zebra offers many connectivity and interface options, including USB, Ethernet, and 802.11b-standard wireless networking.

C o n c l u s i o n

Pharmacists should review their organization's labeling needs in light of JCAHO requirements, ASHP recommendations, and patient safety goals. Bar code control systems for medication dispensing and administration provide proven and significant safety benefits and can be developed independently of larger and more expensive CPOE and EMR programs. Pharmacists are well positioned to drive bar code-based patient safety initiatives and to reap immediate benefits from unit-dose labeling. If computerized patient management systems are added later, bar coding applications can be integrated to support them. Therefore it is important to choose bar code equipment that supports leading clinical information systems and networking standards so it can be scaled to support future plans.

Zebra Technologies is a world leader in bar code, RFID, and ID card printing, with an installed base of more than 4 million units, including systems at healthcare facilities for unit-dose labeling, prescription labeling, patient wristband printing, materials management, asset management, security, and employee identification. Together with its authorized healthcare partners, Zebra has the experience, industry knowledge, and specialized products needed for successful pharmacy implementations. Zebra is also a leader in standards development and actively participates in the work of healthcare industry associations so that it will be prepared to meet the emerging needs of its customers. Contact Zebra at +1 800 423 0442 or visit www.lifesciences.zebra.com for more information about its bar code print solutions for hospitals.



Zebra Technologies

333 Corporate Woods Parkway
Vernon Hills, IL 60061-3109 U.S.A.
T: +1 847 793 2600 or +1 800 423 0442
F: +1 847 913 8766
www.zebra.com

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