



# Improve Patient Safety and Business Processes with Unique Device Identification (UDI)

## UDI is here — are you ready?

Recent legislation has changed the rules for tracking and tracing medical devices. As experts in solutions for product identification and the needs of the healthcare industry, Zebra understands the implications this legislation will have on your business.

To help improve patient safety worldwide, the FDA and European commission defined and adopted Unique Device Identification (UDI) standards to enable complete traceability of the millions of individual medical devices utilized for patient care. In order to safeguard quality and compliance, all medical devices must now carry a Unique Device Identification (UDI) label to enable “track and trace” from the point of production, during shipment, through the product’s safe and appropriate use and finally, to its disposal. The resulting visibility enables clinicians to check the model number, expiration date and recall status of an implantable device before a procedure begins. And faulty medical equipment and implants can be immediately identified and pulled from anywhere in the supply chain to protect patient safety.

In order to ensure traceability of medical devices:

- The UDI label must be recognizable, readable and scannable throughout the entire device lifecycle — from the point of production, during shipment, through the product’s safe and appropriate use and finally, to its disposal.
- Manufacturers and distributors need to scan the UDI labels on the device as it comes off the production line, as well as on the outer packaging to track the device from the moment it is placed on the warehouse shelves to the moment it is shipped to a customer.
- Upon receiving inventory and at the point of care, hospitals and other healthcare facilities can capture, parse and send this UDI data on single or multi-unit device packages to their Electronic Health Record (EHR) or other application.

The time for UDI is now. FDA compliance in the U.S. is currently in place, with European Commission compliance commencing in 2021. Are you ready to unlock the benefits of UDI to improve patient safety and workflow efficiency?



## Implementation challenges

Scanning UDI information can present numerous challenges for manufacturers, distributors and healthcare providers, including:

- **Workers need to be able to seamlessly capture UDI data.** Medical device packaging labels include multiple UDI formatted barcodes, all of which need to be captured and parsed accurately. If workers need to enter information manually, it increases the chance of data entry error.
- **Support for all UDI structures and standards.** Multiple accredited UDI issuing agencies have their own format and specifications.
- **The need to capture multiple barcodes on individual items.** UDIs can be presented as a set of barcodes and workers may also need to scan other non-UDI formatted 1D and 2D barcodes. To avoid scanning the wrong barcode, workers typically resort to covering up nearby barcodes — a time-consuming task that reduces productivity and accuracy.
- **Scanning support for direct part marked (DPM) UDIs.** Since the standards require UDIs to be permanently embedded directly on some single unit devices via a direct part mark (DPM), hospitals and other healthcare facilities will need scanners that can capture DPMs.



## The solution: easily capture and enter UDI information into your application with advanced scanning technology from Zebra



Zebra's UDI Scan+™ makes it easy to accurately capture UDI data and populate the right fields in your application within seconds. This complimentary Zebra DataCapture DNA tool will enable you to unlock the benefits of UDI to increase patient safety, better manage implantable devices, as well as comply with manufacturing regulations.

- **With UDI Scan+, our scanners can automatically recognize and scan the UDI formatted barcode** — A single scan captures it all, virtually eliminating the chance for human error. Users simply scan the barcode on the medical device packaging. The UDI barcode data is automatically parsed, properly formatted and sent in the right order to the right fields in your application. No worker training required, no time spent determining which barcode to scan — just point-and-shoot simplicity.
- **Our scanners will support all UDI standards** — Whether you need to capture GS1, HIBCC or ICCBBA UDI formatted barcodes, UDI Scan+ captures them all.<sup>1</sup>
- **Our scanners can automatically capture multiple barcodes with one trigger pull** — UDI Scan+ works together with Multi-Code Data Formatting (MDF), another Zebra DataCapture DNA tool, to streamline data capture on packages that contain a mix of barcodes. With MDF, your Zebra scanner can capture multiple barcodes with a single trigger pull — and transmit them in the precise order your application needs.
- **Our scanners can capture direct part marks** — Select Zebra scanners can accurately and easily capture DPMs in addition to paper labels.



# Zebra Scanner Portfolio for the Healthcare Supply Chain

MEDICAL DEVICE MANUFACTURER AND HOSPITALS/HEALTHCARE FACILITIES		HOSPITALS/HEALTHCARE FACILITIES	
Warehouse/Storage Room		Patient Facing Areas	
	<p><b>3600 Ultra-Rugged Series</b> The 3600 Series goes to the extreme to keep you working in the most punishing environments. Choose from 18 ultra-tough corded and cordless models, including high density, direct part marks, extended range scanning and more. Virtually indestructible, the series boasts the highest drop, tumble and sealing specifications.</p>		<p><b>DS8100 Series for Healthcare</b> Every feature of the DS8100-HC Series is designed to elevate care. This highly flexible series can be used anywhere, from patient rooms to operating rooms to hallways and local floor equipment storage areas. Industry first housing helps offer maximum protection against the spread of infection and supports the widest range of disinfectants. Choose between corded and cordless models. These premium scanners offer swappable power options and unparalleled scanning performance on IV bags, foil med-packs and other items that competitive scanners struggle with.</p>
	<p><b>DS8100 Series</b> Ideal for non-rugged warehouse environments, the DS8100 Series delivers the ultimate in handheld scanning. This series offers corded and cordless models, swappable power options, unprecedented scanning performance that instantly captures even the most problematic barcodes and innovative productivity enhancing tools that take you beyond the barcode.</p>		<p><b>DS4600 Series for Healthcare</b> This versatile corded healthcare scanner does more for your whole hospital. Its disinfectant ready housing can handle regular sanitizing with popular disinfectants to prevent the spread of infection. Fast, easy scanning on even the most problematic barcodes combines with innovative features that further boost workflow efficiency and the patient experience.</p>
	<p><b>DS4600 Series</b> With the versatile corded DS4600 Series, you get class-leading performance, a large sweet spot, industry leading decode range and a variety of value-added features. A range of models includes a light industrial model capable of capturing direct part marks and high density barcodes, nearer and farther than a general purpose scanner.</p>		<p><b>CS60 Series Companion Scanner for Healthcare</b> The ultra-versatile CS60-HC Series adapts to any clinician workflow and offers a disinfectant-ready housing that helps offer the maximum protection against the spread of infection and supports the widest range of disinfectants. Its groundbreaking design easily converts between corded and cordless operation, handheld and hands-free, as your needs change for superior investment protection.</p>

HOSPITALS/HEALTHCARE FACILITIES	
Pharmacies and Labs	
	<p><b>DS9300 Series</b> The DS9300 Series is designed for handsfree scanning and is compact enough to fit in the most space constrained pharmacy counters. Outstanding swipe speeds and a wide field-of-view combine with best-in-class performance.</p>
	<p><b>DS9900 Series</b> Purpose-built for medical labs and pharmacies, the DS9900 Series improves workflow efficiency and accuracy. Workers get first-time, every time capture of the barcodes found in labs including small, high density, curved and color-coded. An RFID model combines barcode scanning with RFID capabilities to read RFID tags on blood bags and other specimen samples.</p>

## The Right Solution for the Job

In addition to support for UDI Scan+ that streamlines the capture of UDI data, Zebra scanners are loaded with features that bring a new level of task speed, ease of use and accuracy to your workflows...

- **Unparalleled scanning performance.** As equipment travels throughout the supply chain, exposed barcodes can be scratched, smudged or damaged in other ways. Zebra's exclusive PRZM Intelligent Imaging technology ensures that your workers can quickly and accurately capture even the most problematic barcodes, including dense, poorly printed, crinkled, faded, distorted, dirty and damaged barcodes. You can count on dependable first time, every time scanning to minimize manual data entry and the resulting potential for errors.
- **Designed for constant disinfecting.** Zebra healthcare scanners designed for patient-facing environments feature disinfectant-ready plastics that help protect patients and staff from the spread of bacteria, viruses and other germs.
- **Day and night modes.** Available on select models, vibration feedback minimizes noise in the patient's room, admissions desk or lab. With night mode, workers can switch between vibration feedback and beeper feedback in seconds.
- **A durable design that's built to last.** You can count on years of dependable service for the lowest total cost of ownership (TCO).
- **Industry-preferred configuration tools.** Configuring your Zebra scanner is as simple as 1-2-3 with our user-friendly 123Scan Wizard. Intuitive enough for first-time users, 123Scan will walk you through the process of configuring your scanner to capture the right UDI information in the precise order your application requires.
- **DataCapture DNA — transforming scanners from the inside.** Hardware is just the start of what you need to maximize the value of your scanners. Zebra scanners are powered by DataCapture DNA, a set of unique development, management, visibility and productivity tools that lower your TCO and help workers get more done each day.
- **No issues. No surprises.** What makes a scanner top-of-the-line? It's scanning abilities. The ability to scan torn, wrinkled barcodes or withstand harsh work environments, Wi-Fi® interference, battery issues and the like. Whatever you encounter has been anticipated so it can be handled consistently, instinctively and without incident. You can just scan.

**Unlock the benefits of UDI to improve patient safety, increase staff efficiency and comply with manufacturing requirements.**  
For more information, please visit [www.zebra.com/udi-scan](http://www.zebra.com/udi-scan)



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