

Application Brief

Healthcare Unique Device Identification (UDI) Labeling

Industry
Healthcare

Products
Duratran II polyester labels
TMX3000 series resin ribbons
PF8
PM4i

Region
North America

Typical Applications
Medical Device Traceability

Customer Benefits

- Durable printed labels that last for the life of the device
- Assured compliance with government and industry standards
- Improved item traceability
- High contrast print for consistent scanning performance
- Reduced total cost of ownership with free printhead replacement program when Intermec media and fixed printers are used together
- On-demand generation of high quality labels for item traceability
- Stock media items available for quick shipment



Industry Need

The FDA's developing UDI (Unique Device Identification) standard highlights the capacity of auto-ID technologies to enable significant improvements in patient safety. Quick, effective recalls and adverse event reporting are difficult with current medical device management systems, and UDI is targeted to drive major enhancements. Pushing traceability to the device level enables manufacturers and users to quickly identify, locate, and pull recalled units from service; connecting adverse events to a unit serial number can reveal failure trends previously missed with manual checks.

The FDA is developing the unique attributes with input from the GHTF (Global Harmonization Task Force) for Automatic Data Collection of the device's lot and serial number to maintain a chain of custody record for the life cycle of the Medical Device.

Additional benefits to full implementation include accurate device usage data yielding improved maintenance effectiveness. Direct input of device usage into electronic health records can provide significantly increased accuracy of patient service history and billing. Selecting the correct printers and media help ensure UDI labeling delivers the intended benefits in challenging healthcare environments.

Reference Links

FDA Unique Device Identification overview

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers/default.htm>

Intermec Solution

With periodic exposure to fluids, frequent handling, and regular disinfection, healthcare settings can quickly degrade common label materials. Intermec Duratran II polyester labels, paired with TMX3000 series resin ribbons, provide the durability required to ensure survival for the life of the medical device. High tack adhesive provides a strong bond with typical metal, plastic, and painted surfaces; high performance adhesive satisfies labeling requirements on textured surfaces. With off-the-shelf UL recognition, these products are ready for streamlined implementation in device manufacturing processes.

Premium print quality provides easily scanned 1D and 2D symbols, enabling smooth implementation with existing IT systems. Printing on demand with Intermec thermal printers such as the PM4i, this durable labeling system provides the flexibility to satisfy the Unique Device Identification for Medical Devices through distribution and field use.

Media Recommendation

Duratran II 2 mil polyester with high tack adhesive
Duratran II 2 mil polyester with high performance adhesive

Ribbon Recommendation

TMX3000 series resin ribbon

Printer Recommendation

PM4i Mid Range Printer [Profile](#)

- **Smart** – Powerful smart-printing capabilities enable error-proof labeling and can simplify processes; all-in-one printer language abilities for drop-in simplicity
- **Strong** – Superior throughput, designed to excel in demanding environments
- **Secure** – Industry leading, advanced and secure network connectivity options

PF8 Desktop Printer [Profile](#)

- **Easy to Deploy** – Features internal Ethernet option and robust configuration tool
- **Easy to Install** – Uses common media and printer languages
- **Easy to Use** – Drop-in label loading and largest ribbon capacity

The Intermec Advantage

When patient safety hinges on reliable traceability, it is essential that UDI labeling system components work together flawlessly. Intermec printers and media are optimized to deliver superior performance when used together. Our rigorous testing and co-engineering ensures consistently high print quality, proven label and tag performance in demanding real-world environments, and maximum print head service life for reduced downtime.

Intermec printers and media are complemented by the industry's only complete line of integrated solutions and services, including rugged mobile computers, RFID systems, and advanced scanning technology. Intermec products and services are used by customers worldwide to improve the productivity, quality and responsiveness of their business operations.

Printhead Replacement Program

Intermec will provide no cost replacement printheads, as failures occur due to normal wear and tear, to those customers who use Intermec Media Products exclusively with their Intermec direct thermal and thermal transfer fixed printers. For full details, click [here](#).

For more information

Contact Intermec for more information on printers and media for UDI traceability.



123.456.7890
info@YourURL.com
www.YourURL.com



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