HEALTHCARE UNIQUE DEVICE IDENTIFICATION (UDI) LABELING

Industry Need
The FDA’s Unique Device Identification (UDI) 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 Global Harmonization Task Force (GHTF) for automatic data collection of the device’s lot and serial number to maintain a chain-of-custody record for the lifecycle 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 significantly increase accuracy of patient service history and billing. Selecting the correct printers and media helps ensure that UDI labeling delivers the intended benefits in challenging healthcare environments.

SUMMARY

Industry
Healthcare

Product
• FanTastock™ Label
• ThermaMAX™ TMX3000 Thermal Ribbon
• PC43 Desktop Printer
• PM43 Industrial Printer

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 Honeywell free printhead replacement program
• On-demand generation of high-quality labels for item traceability
• Stock media items available for quick shipment
Reference Links
FDA Unique Device Identification overview
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

Honeywell Solution
With periodic exposure to fluids, frequent handling and regular disinfection, healthcare settings can quickly degrade common label materials. Honeywell FanTastock 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 Honeywell thermal printers such as the PM43, this durable labeling system provides the flexibility to satisfy the UDI for medical devices through distribution and field use.

Printer Recommendation

PM43 Industrial Mid-Range Printer
Ready – Fastest to deploy. Seamlessly fits into any environment.
• Large color, multilingual, tamper-proof touchscreen or icon user interface
• No-touch configuration capabilities
• Only CCX and Wi-Fi certified fixed printers with standard IPv6 implementation

Reliable – Maximize uptime. Built from 40 years of printing innovations. Third-generation platform.
• Precision Print for consistent barcode printing with pinpoint accuracy
• Multilingual web page loaded on every printer ensures easy device monitoring
• Strong metal structure with metal door that can be locked for media protection

Perform – Increase productivity and process efficiencies.
• Fastest throughput in its class
• Powerful programmable capability with ability to directly connect peripherals
• Most connectivity options in the market

PC43t Desktop Printer
Intuitive – Super easy to install and use.
• 10-language LCD or icon graphical user interface maximizes uptime
• One-hand media loading for trouble-free use
• Fastest throughput in its class at 8 ips
• Quick configuration with USB stick device

Flexible – Fits your business needs today and tomorrow.
• User-installable connectivity upgrades and accessories for scalability
• Leading command languages for seamless deployment
• Modular IT-friendly design speeds up deployment and support

Smart – Keeps you informed and productive.
• Remote status updates with Honeywell tools minimize downtime
• Programmable with ability to directly add keyboard or scale improves efficiency

The Honeywell Advantage
When patient safety hinges on reliable traceability, it is essential that UDI labeling system components work together flawlessly. Honeywell 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 printhead service life for reduced downtime.

Honeywell 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. Honeywell products and services are used by customers worldwide to improve the productivity, quality and responsiveness of their business operations.

**Printhead Replacement Program**
Honeywell will provide no-cost replacement printheads, as failures occur due to normal wear and tear, to those customers who use Honeywell Media Products exclusively with their Honeywell direct thermal and thermal transfer fixed printers. For full details, click here.

**For more information**
Contact Honeywell for more information on printers and media for UDI traceability.

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**Media Solutions for Unique Device Identification**

<table>
<thead>
<tr>
<th>MATERIAL</th>
<th>DURABILITY</th>
<th>TEMPERATURE RANGE</th>
<th>MANUFACTURER UDI</th>
<th>END-USER DURABLE LABELING</th>
<th>ASSET TRACKING</th>
<th>LEADING STOCK LABEL CONFIGURATIONS</th>
<th>LEADING STOCK RIBBONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>FanTastock Label</td>
<td>Best 7+ years outdoor; superior scratch, smudge and chemical resistance</td>
<td>10°C (50°F) minimum application, -40°C to 150°C (-40°F to 302°F) service; evaluate up to 249°C (480°F)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>1 in x 2 in (E23067), 1.25 in x 3 in (E23070), 2 in x 1 in (E10164), 3 in x 1 in (E23068), 3 in x 2 in (E23069), 4 in x 1 in (E25732), 4 in x 6 in (E25733)</td>
<td>TMX3000 Series: 2.09 in x 18,000 in (13632018), 3.27 in x 12,000 in (1303332), 4.1 in x 18,000 in (13634118)</td>
</tr>
<tr>
<td>FanTastock HP Label</td>
<td>Best 7+ years outdoor; superior scratch, smudge and chemical resistance</td>
<td>10°C (50°F) minimum application, -40°C to 150°C (-40°F to 302°F) service; evaluate up to 249°C (480°F)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>3 in x 1 in (E27277)</td>
<td>Custom</td>
</tr>
</tbody>
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For more information
www.honeywellaidc.com

Honeywell Safety and Productivity Solutions
9680 Old Bailes Road
Fort Mill, SC 29707
800-582-4263
www.honeywell.com

In a continuing effort to improve our products, Honeywell reserves the right to change specifications and features without prior notice.

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