Technology White Paper

Direct Part Marking

The Basis for Cradle-to-Grave Traceability

OMRON

MICROSCAN

Old DPMs never die, nor do they fade away. At least they're not supposed to meet their demise before the part carrying them goes out of service. One of the major challenges of using DPMs (short for "direct part marks") to trace products and parts lies in the need for permanence. If a part is to be incorporated into a brand-new Boeing 737 and the aircraft is expected to stay in service for several decades, then the DPM on that part needs to last several decades as well. This is known as "cradle-to-grave traceability" – a fundamental requirement for the sake of quality control and public safety.

Cradle-to-grave traceability wouldn't be possible without those cryptic little symbols, many of which look like something that might be carved into the walls of an ancient Mesopotamian tomb. DPMs of a variety of types – ink jet, laser etch, dot peen and more – serve as the machine-readable identification codes that link the physical world of airplanes, PCBs and surgical instruments to the ever-expanding world of digital tracking data.

When a device or a part is traceable throughout its lifetime, manufacturers and oversight bodies can more effectively enforce high quality standards and efficiently implement recalls whenever the need arises. This helps ensure that faulty devices are removed from the market quickly when their flaws come to light. Cradle-to-grave traceability also plays a major role in preventing part counterfeiting. Since tags, stickers and other types of indirect markings don't necessarily remain with their corresponding objects, manufacturers turn to DPMs to ensure complete life-cycle traceability.

This white paper will discuss:

- *How DPMs benefit industries*
- *How DPMs encode data*
- *The importance of DPM verification*

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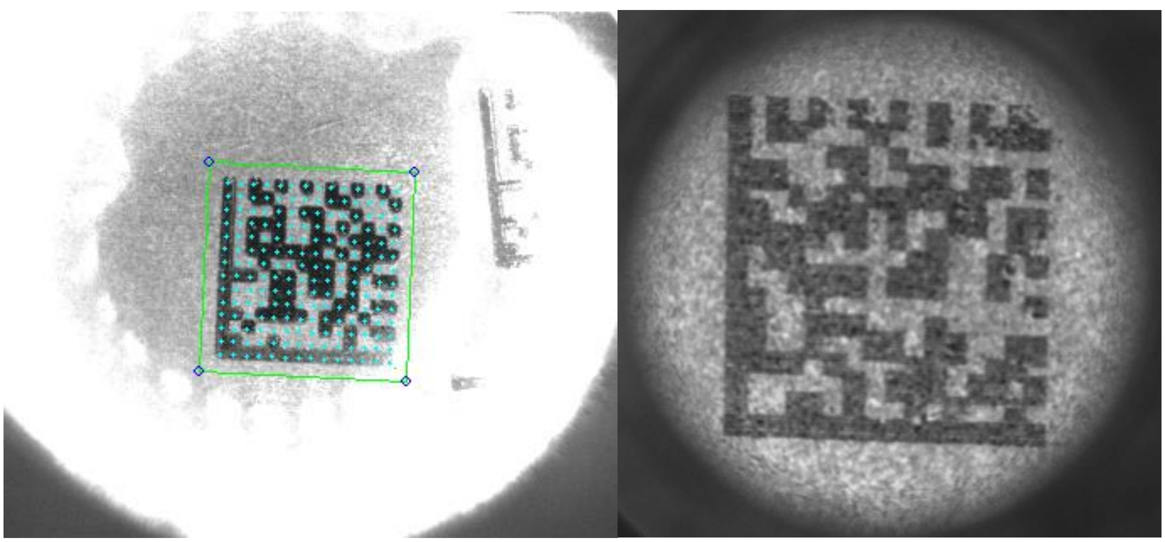

Figure 1: *Examples of direct part marks (DPMs) as seen by an industrial code reader.*

How Direct Part Marking Facilitates Traceability Across Industries

DPMs have become a staple of numerous industries, including consumer electronics, automotive manufacturing and aerospace manufacturing. From tiny printed circuit boards (PCBs) to giant aircraft components, each part and device acquires a stamp of sorts that brings it under the auspices of a tracking database.

Several industries, such as medical device manufacturing, have implemented mandatory systems of DPM-facilitated traceability on a nationwide or even international basis. The more safety is a concern, the more likely it is that the law will require a device or part to bear a permanent mark of identification.

Figure 2: *Direct part marking is indispensable in the aerospace industry. Many aircraft parts are expected to remain traceable for several decades.*

Traceability in the Medical Industry

The United States Food and Drug Administration (FDA) has been making sizable efforts to promote a comprehensive traceability system for all medical devices. These devices have been divided up into three categories regarding their potential for causing harm to patients. Relatively simple, harmless tools like bandages and examination gloves belong in Class I, whereas complex, life-saving devices like pacemakers fall under Class III. The traceability requirements – including whether or not a DPM is mandatory – vary for each device class. The upcoming deadline of September 24, 2018 is burned into the brains of most medical device manufacturers because that's the date when all reprocessable, multi-use Class II devices will need to bear DPMs encoding the unique device identifier (UDI).

Medical device manufacturers intending to sell their products on the European market will run into a similar set of regulations known as MDR & IVDR (short for "medical device regulations" and "in vitro diagnostic regulations"). The content of each set of regulations is similar to FDA UDI, with device registration deadlines (Spring 2020 for MDR and Spring 2022 for IVDR) followed by labeling deadlines based on device class.

Figure 3: *A hospital worker places a set of surgical instruments into an autoclave for sterilization. Each of these instruments will soon need to bear DPMs that can withstand multiple sterilization treatments.*

It can be a challenge for device manufacturers to affix DPMs, especially when space is limited. Many surgical instruments, such as arterial clamps, don't offer much room for a two-dimensional, data-packed code. Furthermore, these markings need to be able to withstand repeated sterilization treatments that use high heat and sometimes harsh chemicals. Fortunately, laser marking technologies have advanced to the point where durable codes as small as 2 mil – or two thousandths of an inch – can be applied to delicate surgical instruments. (To give an idea of how small this is, imagine a tiny barcode that is barely larger than the tip of a pencil.) These advancements mean that more instruments can be marked with DPMs, but it also creates the necessity for barcode readers that can decode such miniscule markings.

Although the various regulations mandating direct part marking for specific classes of medical devices is primarily meant to promote patient safety, this practice can have other benefits for hospitals as well. For instance, when hospital staff assemble surgical trays, they no longer need to use a printed checklist with the names of every instrument and the exact combination needed. Instead, they can simply scan devices to make sure they have the full set ready to go. This makes the assembly process faster and more fool-proof.

Traceability in the Automotive Industry

Given the intense pressure of global competition and an increasingly informed, quality-minded consumer base, automotive manufacturers have found comprehensive traceability systems to be essential. These systems focus on documenting the origin of all parts and the subassemblies that correspond to specific vehicle categories so that they can be tracked throughout their manufacturing and distribution.

Implementing such a system can be a huge investment in both time and cost, given that a manufacturer would need to mark as many as 20,000 different parts for just a single automobile. However, the payoff in terms of quality control and other business operations makes the effort worth the cost. Full traceability can provide reams of data that can in turn be used for such purposes as inventory control, revenue forecasting, output calculations, warranty and more. It can also facilitate real-time tracking systems to monitor where a given part is at a given point in time – a process that aids in discovering the sources of bottlenecks on the assembly line.

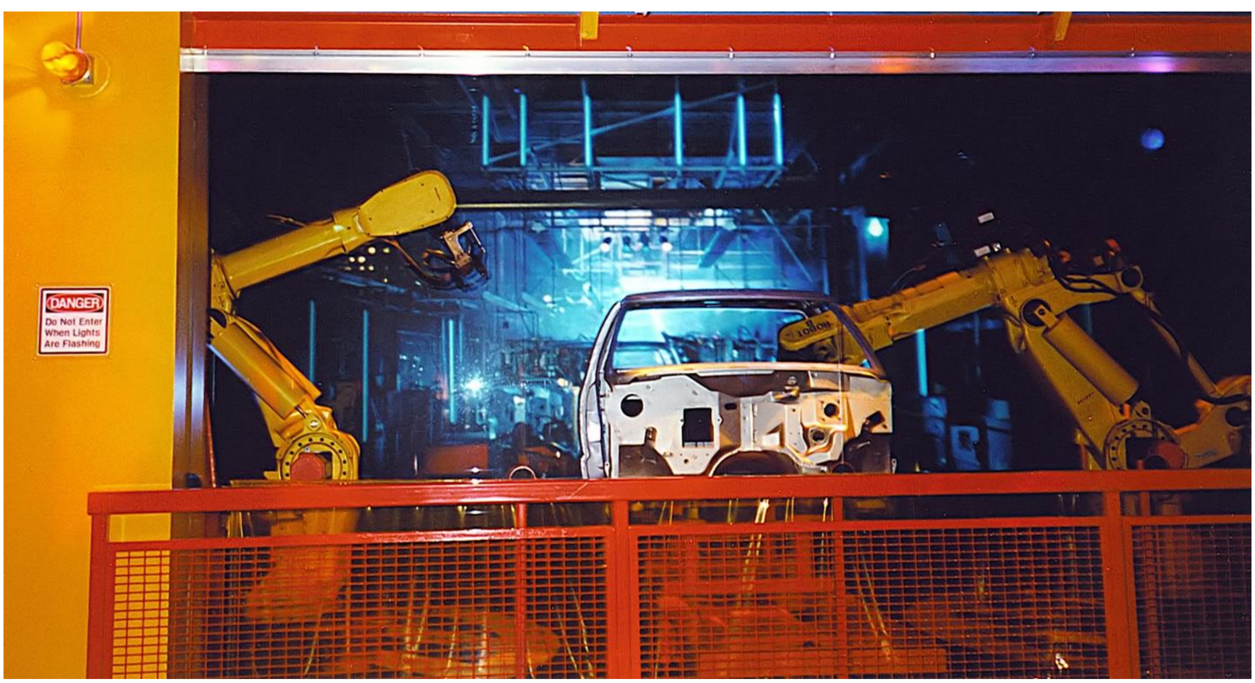

Figure 4: *A pair of robots assemble a vehicle. Direct part marking provides a crucial means of tracking automotive parts throughout their service.*

To ensure that DPMs remain viable throughout the automotive production process, it's important that the marking method can withstand harsh conditions. For this reason, abrasion-resistant marking methods such as laser marking, dot peening and electrochemical etching are commonly used in the automotive industry.

Cracking the Tracking Code

The information housed in a DPM varies by industry, but it generally includes any data deemed essential to tracking a part or product's whereabouts and determining where it originated. For medical device UDI compliance, the required information is the device model and its manufacturer. Optional data may include lot number, serial number and manufacture date. For automotive manufacturing, parts are usually stamped with codes that specify source manufacturer, place of origin, lot number, part number, serial number, production time and date, and manufacturing facility.

Depending on the amount of data needing to be encoded and the surface available for DPM placement, manufacturers may choose one of several linear or two-dimensional formats for encoding data. These are known as symbologies.

Linear Symbologies

Laser scanners can only read along one axis, so they require one-dimensional barcodes. Although linear barcodes may be mandatory if laser scanners are the only type of reading device available, they don't offer room for much data. Two-dimensional codes can pack in far more data, although the decode speed (using imagers rather than lasers) is much slower than it is for linear codes.

Figure 5: *Laser scanners like Omron Microscan's QX-870 offer high-speed reading but can only read linear barcode symbologies.*

The Data Matrix Symbology

Recommended by the U.S. Electronic Industries Alliance (EIA) for labeling tiny electronic components, the Data Matrix is a two-dimensional arrangement of dark and light cells in a grid. Because it often incorporates error correction codes, the symbology allows for several of the cells to be damaged without sacrificing readability. Every Data Matrix has two adjacent borders composed of all dark cells (known as the “finder pattern”) and two other borders with alternating dark and light cells (known as the “timing pattern”). These components are important for alerting imagers to the presence of a code and specifying how many rows and columns the symbol contains.

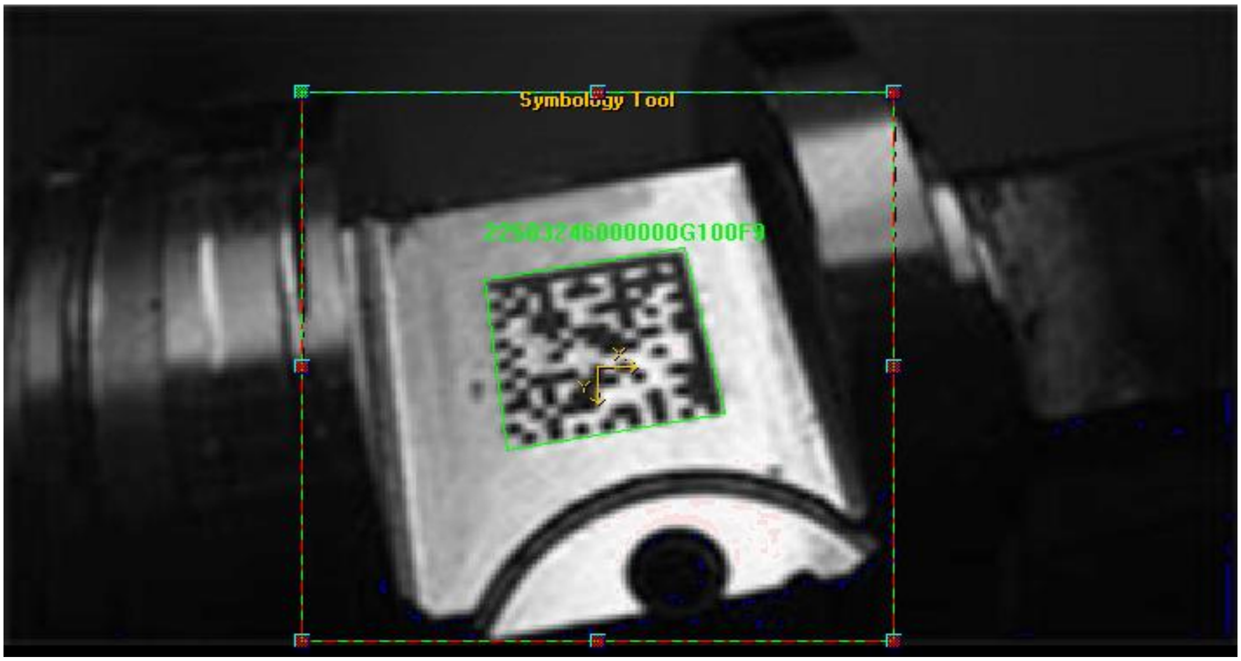

Figure 6: *A Data Matrix on a metal surface. Can you spot the finder pattern and the timing pattern?*

The QR Code Symbology

Used by some automobile industry manufacturers, the two-dimensional QR Code (short for “Quick Response”) can vary widely in size and complexity through the addition of extensions. Although it has a large storage capacity, it can still be read quickly – a trait that makes it ideal for high-throughput production environments. This symbology originated in Japan because other formats didn’t allow for the inclusion of complex characters like kanji. It uses a two-dimensional grid pattern of dark and light cells similar to a Data Matrix.

The symbology of choice depends on several considerations, including the amount of space available, the amount of data to include and the likelihood that part of the code will be damaged at some point. Some applications, such as those that require minimal data to be encoded onto a flat, non-reflective surface, could get by with simple linear barcodes. Other applications requiring data-packed symbols to appear on all sorts of rough, shiny, curved or otherwise non-ideal surfaces might require a two-dimensional symbology like Data Matrix or QR Code.

The Importance of Verification

The sheer variety of direct part marking options poses a significant challenge in terms of readability. Since a part's entire use history could be lost when a DPM fades or erodes, verification is of the utmost importance. No manufacturer wants to have to pull a perfectly good part from service simply because its identifying mark has bitten the dust.

To ensure that DPMs of all types are readable, today's advanced verification systems grade the markings against several criteria specified by the International Organization for Standardization (ISO). Important criteria for two-dimensional DPM symbols include – but are not limited to – the following:

- **Cell Contrast**: The difference in intensity between the light and dark elements of a symbol.
- **Cell Modulation**: The consistency in reflectance throughout a symbol. For instance, if some of the symbol's "dark" elements were black and others were more of a light gray, the symbol would get a low modulation grade because its reflectance is inconsistent.
- **Axial Non-Uniformity and Grid Non-Uniformity:** Two measurements that indicate how much a symbol deviates from the ideal, square grid pattern with perpendicular rows and columns. Axial non-uniformity measures the vertical and horizontal stretching, whereas grid non-uniformity refers to the stretching along diagonal lines.
- **Fixed Pattern Damage**: The degree to which mandatory elements (such as the finder pattern and timing pattern of a Data Matrix symbol) are damaged or missing.

Figure 7: *A handheld verifier checks the readability of a miniscule DPM.*

In addition to ensuring readability throughout the lifetime of a device, a verification system helps monitor the functioning of marking equipment. If the ink jet printer is running out of ink, the grading data will show that contrast is going down over time. Similarly, if the stylus of the dot peen machine is wearing down, then the verification system will show a trend in dot size changes.

Summary

Although complex, the practice of directly marking parts and devices is essential for tracking these items throughout their service. A thorough implementation of cradle-to-grave traceability helps manufacturers identify quality issues, speed up bottlenecks and keep the public safe from faulty products. Manufacturers can take stock of the particular challenges posed by their tracking data requirements and the shape, material and expected lifetime of their products to choose an appropriate DPM symbology and marking method. A solid tracking system built upon the appropriate choice of DPM can provide a significant return on investment in addition to ensuring compliance with key regulatory standards.

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