



## **The Health Industry Bar Code (HIBC) Standards:**

### **F.A.Q.s for the Global Supply Chain**

#### **1. IS EPC RFID THE DE FACTO STANDARD IN HEALTHCARE OR ANY OTHER INDUSTRY?**

**No.** RFID technology is not exclusive to ePC as it already exists and is employed with other standards, including ISO 18000. It is a false assertion that ePC will be the only standard for RFID.

Healthcare and other industries have already begun implementation of RFID without the use of ePC. Medical device suppliers that require item level RFID are more likely to look to 13.56 MHz, under existing ISO 18000 standards. The HIBC LIC and associated data structure can be easily accommodated by current ISO 18000 standards.

In fact, a major HIBC manufacturer has already implemented RFID for tracking implants using the HIBCC LIC and data identifiers to code onto a 13.56MHz tag which conforms to ISO 18000.

Likewise, numerous other industries are implementing RFID through ISO standards without the need for ePC. Recently, the Joint Automotive Industry (JAI), a collaborative initiative within the global automotive industry, and whose members include Automotive Industry Action Group (AIAG), Japan Automotive Manufacturers Association (JAMA), Japan Auto Parts Industries Association (JAPIA), Odette International Limited, Standards for Technology in Automotive Retail (STAR), has made a global announcement rejecting the ePC standard for the automotive industry. Odette further went on to say that ‘we are collectively not prepared to recommend the usage of ePC or give any endorsement to it and will always work towards open standards.’

#### **2. DOES THE U.S. DEPARTMENT OF DEFENSE (DoD) UNIQUE IDENTIFICATION (UID) INITIATIVE MANDATE EPC?**

**No.** Although the DoD accepts ePC numbering, it is not mandating its use. DoD supports the use of Data Identifiers as defined by ANS MH.10.8.2, which is not dependent on ePC and its requisite licenses. In fact, DoD has been quite emphatic and vocal about making it clear that they will not rely upon ePC as a sole source in this regard.

Further, most of the DoD UID effort is related to 2-D coding (specifically Datamatrix), not RFID, as its purpose is for individual unique identification of products. RFID efforts relate to case/pallet identification. The HIBC Standards fully support Datamatrix for small package labeling as well as RFID applications.

### **3. IS THE HIBC A VALID DATA FORM FOR THE DoD UID?**

**Yes.** The DoD specification accepts the ANS MH.10.8.2 standard, which includes HIBC as a valid data identifier. As such, the HIBC complies precisely with the DoD UID.

EHIBCC/HIBCC is a registered Issuing Agency (IA) of the prefix “LH” which can be used by all HIBC labelers. (HIBCC and EHIBCC have agreed to share the prefix assignment.) Contrary to misconceptions, HIBC Labelers do not need to register for their own prefix as HIBC LICs are distinct and unique.

### **4. IS THERE ANY LINK BETWEEN U.S. DoD EFFORTS AND EPC TO JUSTIFY THE TWO IN COMBINATION AS A “DRIVER”?**

**No.** There are critical limitations within ePC that will limit its significance for DoD or any other user. The ePC structure is based upon the EAN/UCC numbering system, which in many countries restricts users to a 3-digit product code. Because of the need by EAN/UCC to preserve numbers, it issues 9-digit company prefixes, which limits the product code to 3-digits. As such, ePC inherits the limiting factors of EAN/UCC that limits its importance in healthcare.

ePC Global remains in its infancy. It is still only in trials, limited to the distribution level and not extended to item level packaging. There are numerous issues with UHF, the ability to “stack” ePC Gen 2 tags, obtain accurate readings, etc.

### **5. DOES SERIALIZATION LEAD TO EPC? IS EPC PARTICULARLY WELL-SUITED TO SERIALIZATION?**

**No.** Serialization within the HIBC, if ever necessary, can already be accomplished. (See Data Identifiers specified in ANS MH.10.8.2 or under DIN V 66401.)

Serialization likewise does not lead exclusively to RFID. Serial numbers can be encoded using multiple data carriers - linear barcodes, 2-D symbols (Datamatrix, etc) and RFID. However, space constraints on packaging may make 2-D and RFID applications more practical.

Implementation of serialization using the HIBC data structure allows HIBC labelers to maintain and preserve their established labeling processes – the benefits of which are significant in terms of backward compatibility and associated costs.

### **6. IS THERE AN ESTABLISHED ROLE AND NEED FOR SERIALIZATION? DOES IT PROVIDE A RATIONALE FOR STANDARDS MIGRATION TO AN EAN SYSTEM?**

**No.** There is no technical basis or business case to support a migration to EAN/UCC. To support serialization, manufacturing processes will change at their most fundamental levels. Information systems will likewise have to change to accommodate the identification of the thousands of product lines and millions of products that are manufactured and sold. The cost of these system changes is enormous and a more significant and immediate consideration than what code is ultimately applied.



Serialization should not be approached generically, but rather should be considered relative to the need and benefit by product. For instance, a pacemaker that is composed of many different parts that ultimately become one item may warrant serialization for track and trace purposes. However, serialization of batch processed products such as disposables and consumables will provide little to no added benefit.

The cost and use justification for the fundamental changes required to support serialization have yet to be defined by the industry. This concept is at such a preliminary stage that it is not logical to consider it as the basis for standards migration.

#### **7. ARE THERE RISKS ASSOCIATED WITH A REQUIREMENT TO MIGRATE TO AN ALL-EAN SYSTEM?**

**Yes.** A requirement for migration to EAN imposes unnecessary and costly burdens on the entire healthcare supply chain.

Migration to EAN/UCC would require:

- Purchase/maintenance of EAN/UCC licenses globally;
- Updating of global databases;
- Customer data synchronizations;
- Customer system updates;
- Maintenance of duplicate systems for many years, both internally and for customers.

Medical devices have a very long shelf life. As a result they remain in the supply chain for many years. These items are distributed across the globe in tens of thousands of locations. The duplication of systems that would be required is unnecessary and will force significant costs on manufacturers and their customers.

#### **8. SHOULD MANUFACTURERS PROTECT THEIR SIGNIFICANT INVESTMENT IN HIBC STANDARDS?**

**Yes.** Medical/Surgical product manufacturers have largely chosen the alphanumeric HIBC Standards as their preference. The translation and/or cross referencing of alphanumeric codes to an all-numeric format has the potential to lead to errors and as a result has possible patient safety implications.

A migration to the all-numeric EAN/UCC standard will require extensive modification and cross-referencing of product numbers, and would thus weigh heavily against a manufacturer's interest in and reputation as a leader in high-quality patient care.

#### **9. ARE THERE OTHER ADVANTAGES TO THE HIBC STANDARDS?**

**Yes.** The HIBC Standards are globally consistent and thus do not impose the costly and complex regional registrations of EAN.



The HIBC Standards were designed for consistent implementation across international markets and thus are the same everywhere in the world. There are no regional variances. This enables implementation of secure and efficient tracking processes in both domestic and international markets.

EAN/UCC Standards were developed regionally to meet the localized needs of retailers. EAN data formats may be 12, 13, or 14 digits in length depending on origin. Implementation varies by country and by industry and thus requires users to obtain and maintain multiple registrations. This inconsistency imposes significant costs and can lead to problems with database compatibility and inventory management. It can also necessitate the risky and costly process of over-labeling of products.

**10. ARE HIBC STANDARDS ENDORSED GLOBALLY BY THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)?**

**Yes.** ISO is the recognized authority responsible for developing and coordinating standards internationally. It has already advocated the use of HIBC in ISO 22742 for Product Packaging (*Linear bar code and two-dimensional symbols for product packaging*) and supports RFID using HIBC through the ISO 18000 and the ISO 17364, 17366, 17367 standards.

**11. IS THE UNIVERSAL PRODUCT NUMBER (UPN) ESTABLISHED UNIVERSALLY?**

**Yes.** UPN was developed in the mid-1990s (initially by the U.S. Department of Defense (DoD)) for the specific purpose of encompassing both HIBC and EAN/UCC identifiers. The essence of UPN has always been co-existence of the two standards precisely to avoid the unnecessary costs and complications of migration.

UPN is endorsed and advocated by the major global trade associations, including AdvaMed, EUCOMED, HIDA, HDMA and MIAA.

**12. DOES THE UPN SUCCESSFULLY ENABLE POINT-OF-USE DATA CAPTURE?**

**Yes.** Implementation of point-of-use data systems requires the commitment and investment of customers. Lack of implementation is not a result of limitations of either standard, but rather the ability and willingness of customers to support point-of-use processes. Use of EAN/UCC will not increase the likelihood of implementation.

**13. WILL HIBC STANDARDS SUPPORT EVOLVING TECHNOLOGIES?**

**Yes.** The evolution of HIBC Standards to incorporate the use of 2-D symbols and RFID supports the continued use of UPN as the industry standard. This continuity will dramatically simplify the industry's transition to new technologies, thereby reducing unnecessary complication and cost to the supply chain.

