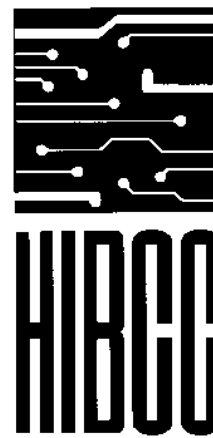


The Use of the Health Industry Bar Code for Product Labeling and Device Tracking



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Background

The Health Industry Business Communications Council (HIBCC) was founded in 1983 by leading U.S. health care associations: American Hospital Association (AHA), Pharmaceutical Research and Manufacturers Association (PhRMA), Health Industry Manufacturers Association (HIMA), National Wholesale Druggists Association (NWDA) and the Health Industry Distributors Association (HIDA). These associations determined that the existing UCC/EAN bar code standards were inadequate for the specific applications and needs of a health care environment, as they were based upon the point-of-sale, “cash register” needs of retailers who did not have patient/consumer safety concerns.

HIBCC’s mission was to design a specialized, yet fully interoperable, bar code labeling standard based upon the critical requirements of a health care environment. As a result, the Health Industry Bar Code Standards were developed.

HIBCC and the HIBC Standards are accredited by the American National Standards Institute (ANSI) and the European Committee for Standardization (CEN). The use of HIBC Standards are endorsed by EUCOMED, the Health Industry Distributors Association (HIDA) and the Medical Industry Association of Australia (MIAA).

HIBCC’s mission is extended globally via IHIBCC, an international network of HIBCC offices.

Features of the Health Industry Bar Code

Alphanumeric Character Set

The HIBC Standards utilize an alphanumeric character set. This allows for literal encryption of a manufacturer’s existing product identifiers into a bar code data structure, eliminating the need for translation of alpha characters into numeric signifiers.

UCC/EAN data structures utilize an all-numeric character set. This requires manufacturers to alter their alphanumeric product identifiers and serial numbers and necessitates a risky and costly cross-referencing process.

Variable Length Data Structure

The variable length data structure allows the manufacturer to incorporate current product identifiers without having to truncate or pad digits.

UCC/EAN data structures are fixed at a specific length. This forces manufacturers to modify their existing product identifiers to fit within the required format. This process also necessitates the cross-referencing of original-to-modified data, greatly increasing the risk of error.

No Risk of Duplication

The 36 alpha and numeric characters combined with the flexibility of a 1-13 digit variable length format, provide an almost infinite set of identifiers – over 75 quintillion (mathematically defined as 75 million trillion). This virtually eliminates the possibility of duplicate identifiers in the same database.

UCC/EAN data structures are limited by a ten digit (0-9) character set and a fixed length format. Because of these restrictions some UCC/EAN formats can only support 100 items with a manufacturer's registration.

Consistent Implementation on All Packaging Levels

The HIBC data structure is consistent for every package level of a product, whether it is a unit of use or a pallet load. Different levels of product are specified within the 'level of packaging indicator' field with manufacturer assigned characters. This simplifies and reduces the risks in building software systems to scan the bar codes. When tracking and traceability for the purposes of recall are at issue, this stream-lining is both critical and essential.

UCC/EAN uses six (6) bar codes for different packaging levels, each with a different length data structure. This complexity greatly increases the probability of error within a bar code scanning system.

Globally Compatible

The HIBC data structures 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.

UCC/EAN data formats can be 12, 13 or 14 digits in length depending on their country of origin. This inconsistency can lead to problems with database compatibility and inventory management. It can also make the risky and costly process of overlabeling of products necessary.

Secure Link Characters

For many medical and pharmaceutical products, especially implant devices, a primary bar code (product identifier) and a secondary bar code (serial number) are required. During the manufacturing process the primary symbol will be structured and labeled first, with the secondary symbol labeled at the end of the assembly.

Only the HIBCs have a 'link' character to prevent the wrong serial number from being matched up with its product identifier. This is a critical feature for ensuring the security and reliability of tracking processes and their extension into the hospital environment.

UCC/EAN bar codes do not have link characters and therefore cannot ensure accurately identified products or reliable tracking processes.

Embedded Data Check Characters

All HIBCs have data check characters to verify the accuracy of the information encoded in the data structure. Check characters also guarantee that the data messages have not been corrupted during transmission. This prevents errors in the scanning of product identifiers and secures the process of product tracking.

UCC/EAN data structures for serial number, expiry date and lot/batch information do not have check characters.

Achieves Interoperability

The HIBC system of standards provides for the identification of medical products and for all health care applications, including the identification of: patients, clinicians, specimen/tissue samples, pharmacy prepared medications, X-Ray films, medical records, facility locations, transplant organs and surgical instruments. These standards enable consistent implementation of the data capture and verification process and facilitate complete interoperability in a networked hospital environment.

The UCC/EAN system does not provide a standards based application for these health care specific requirements and is not capable of secure or accurate communication in a networked environment.

Technologically Advanced

HIBC Standards specify the use of 2-D symbologies, such as Data Matrix and PDF-417, for small device and instrument marking. Both small space symbols have been widely implemented and are supported by readily available technologies. Data Matrix is currently in use within the aerospace and automotive industries for critical parts identification and tracking.

Health care products have unique requirements that are especially well suited to the use of small space symbols. Data Matrix is the only symbol that can be etched directly onto a device and read reliably. It is currently used for marking implantable devices and surgical instruments, providing a more durable and less costly alternative to traditional labeling.

UCC/EAN's small space symbol has not been widely tested or deployed. It cannot be etched onto an implantable device.